Getting Biosimilars To Market - Patent and Antitrust Perspectives

Moderator:
Joy M. Sidhwa
Senior Attorney, MoginRubin LLP

Panelists:
Ali Ahmed
Senior Vice President, Fresenius Kabi, USA
Jonathan (Jon) Berman
Partner, Jones Day
Elaine Herrmann Blais
Partner, Goodwin
Sailesh (Sal) Patel
Partner, Schiff Hardin LLP
Kevin A. O'Connor, Ph.D.
Partner, Neal Gerber Eisenberg

JS: Today's discussion will examine the considerable commercial hurdles that biosimilars face from both an antitrust and patent perspective. Our panelists have been hand-selected based on their extensive experience and knowledge of these issues.

Given the complexity of this topic, it will be helpful to define some of the key terms and legislation at the outset. Biologics are drugs (typically expensive) made from complex molecules manufactured using living microorganisms, plants, or animal cells. Biosimilars are drugs manufactured by a different entity that are highly similar to a reference biologic. The Biologics Price Competition and Innovation Act of 2009 ("BPCIA") provides an abbreviated path for the approval of biosimilars and creates two levels of approval: biosimilar and interchangeable. To be deemed a biosimilar, a drug must be highly similar to and have no clinically meaningful differences from the reference biologic.

To be deemed interchangeable, a biosimilar must satisfy two additional criteria: (1) it must be expected to produce the same clinical result as the reference biologic in any patient and (2) must present no greater risk in terms of safety or diminished efficacy than that of using the reference product. **Sal and Ali – let's begin with a common question from people not familiar with biosimilars. What are some of the key commercial reasons for slow uptake in the U.S. market for biosimilar entrants and what are some potential solutions?**

Certain stakeholders may be skeptical of the efficacy of a biosimilar without clinical studies for each indication, despite the fact that FDA has allowed the approval of the biosimilar product without necessitating additional clinical data.

Ali Ahmed

SP: The single biggest hurdle is interchangeability. While bioequivalence is relatively straightforward in the small-molecule space, the two-tiered "biosimilar" and "interchangeable" hierarchy in the BPCIA creates a significant barrier to market penetration for new entrants. To date there are no approved interchangeable biosimilars. Though the FDA states that both can be used in new and existing patients, there is hesitancy to switch existing patients from a biologic to a biosimilar, despite the lower cost. Without automatic substitution, biosimilars need to brand themselves and market to doctors and patients, negating some of the intended cost savings. Many biosimilar applicants do not have robust marketing capabilities compared to reference manufacturers. Increasing the number of interchangeable biosimilars could significantly increase confidence among patients and providers. Perhaps following the UK model, which requires a large portion of treatment-naïve patients be given lower-cost biosimilars instead of reference products, could help not only incentivize more biosimilars to get on the market, but also improve the perception of biosimilars in the eyes of patients, insurers, and healthcare providers.

In the UK, 90% of new patients will be prescribed the "best value biological medicine" within three months of a biosimilar launch. For existing patients, there is a longer window of one year to be prescribed the "best value biologic" for 80% of existing patients.

AA: Another reason for the limited uptake in the U.S. for biosimilars (especially as compared to other markets such as Europe) is that current contracting strategies and rebate practices of biologics manufacturers have created high barriers to, and thus discouraged, biosimilar adoption. More specifically, reference manufacturers increase rebates to retain market share and formulary exclusivity with payers.

One important distinction between small molecule generic drugs and biosimilars is a greater opportunity for the biosimilar applicant to generate innovations, for example, around new formulations or methods of manufacturing.

Kevin A. O'Connor, Ph.D.

FRESENIUS KABI
caring for life

Ali Ahmed
Senior Vice President, Fresenius Kabi, USA

NEAL GERBER EISENBERG

Kevin A. O'Connor, Ph.D.
Partner, Neal Gerber Eisenberg

JONES DAY

Jonathan Berman
Partner, Jones Day

Furthermore, reference manufacturers will bundle rebates for both naïve and incontestable (legacy) patients and bundle rebates across different products. These exclusive dealing contracts with payers may (1) require insurers to deny coverage for a biosimilar altogether or (2) impose unreasonable preconditions (like a "fail first" requirement) governing coverage for the biosimilar.

Amgen has recently utilized such contracting strategies to protect its NEULASTA market by entering into an agreement with United Health Care, the largest U.S. insurer, on July 1, 2019, which prefers the use of Amgen's NEULASTA over the biosimilar pegfilgrastim options. Amgen is not the only reference manufacturer engaged in such tactics which are contrary to the interests of patients, health care providers and the taxpayers who fund Medicare. Johnson & Johnson has similarly used its contracting strategy to block biosimilar competition for REMICADE by utilizing rebates on a range of their products in return for the insurer's blocking physician and patient access to biosimilar infliximab product. The Federal Trade Commission has recently launched an investigation into the anticompetitive effects of Johnson & Johnson's contracting practices and Pfizer, as well as direct and indirect purchasers of REMICADE, have filed a lawsuit against Johnson & Johnson in 2017. The lawsuit is currently in the midst of extensive discovery after Judge Joyner of the U.S. District Court for the Eastern District of Pennsylvania denied Johnson & Johnson's motion to dismiss. The FTC investigation and lawsuit against Johnson & Johnson are being closely watched by policymakers in Washington since various committees are evaluating novel ways to reduce drug pricing.

JS: Thank you, Sal and Ali. I agree that the pricing and contracting tactics by the biologic manufacturers are primarily to blame for slow biosimilar uptake. For example, as Ali alluded to, Biologic manufacturers have used their market power over existing patient bases (large, non-competitive markets due to existing patients' inelasticity of demand for biologics) to leverage insurance and healthcare companies to enter into exclusivity agreements (or *de facto* exclusivity agreements). These agreements seem to effectively wall off biosimilars from competing for new customers (a competitive market) and/or capturing significant market share.

Numerous antitrust lawsuits allege that payments described by the settling parties as fair payment for services are actually shams designed to disguise improper pay-for-delay conspiracies.

Jon Berman

This practice is at the heart of the pending Johnson & Johnson antitrust litigation. To suppress Pfizer's infliximab biosimilar (Inflectra), Johnson & Johnson purportedly adopted a bundled rebate program that pushed insurance companies to exclude or restrict coverage of inflixomab biosimilars or risk losing the rebates. This strategy has been successful, as roughly 70% of insured patients in the U.S. are covered by plans with these commitments. Due to this lack of coverage and fear of non-reimbursement, approximately 90% of healthcare providers that stock infliximab biologics do not stock the cheaper biosimilar Inflectra. Biosimilars facing these or similar competitive restraints have little hope of capturing significant market share when they are not even offered by most healthcare providers. But pricing and contracting strategies are not the only commercial hurdles erected by the biologic manufacturers. Isn't that so, Elaine?

EB: That is correct. Patent thickets are also posing a commercial hurdle. Even though FDA has approved 23 biosimilar products to date, only 8 have launched commercially in the United States. Several of the products that have not yet launched are subject to patent settlement agreements between the biosimilar manufacturer and the reference product sponsor. Notably, and as has been well reported, the approved adalimumab biosimilar products will not launch in the U.S. until 2023 due to settlement agreements, even though the same products are already on the market in Europe and the original composition of matter patent covering adalimumab in the U.S. expired in 2016. This shows that the significant patent portfolios covering biologics in the U.S. are serving as a means to prevent biosimilar launch upon approval. For instance, vast patent portfolios make it costly and cumbersome for biosimilar manufacturers to plan ahead on patent strategy. More complex cases involving numerous patents also take longer to litigate, which delays final decisions on questions of infringement and validity and could delay biosimilar launch. Also, the more patents there are in the reference product sponsor's portfolio, the more patents are "at play" for assertion in the second wave case. And there are risks associated with those patents that are not litigated in the first wave case.

JS: Let's talk more about settlements between biosimilar and biologic companies. What might future patent litigation settlements between biologic companies and biosimilar entrants look like – as opposed to what we've seen with generic drugs? Kevin, would you like to take this one?

KO: The first wave of patent litigation settlements between biosimilar and biologic companies brought up many familiar issues. However, this first wave of settlements may not be typical of what we see going forward, particularly in terms of the agreed upon biosimilar launch date. For one, the first wave of settlements involved patents covering formulations, methods of using the biologic, and/or methods of manufacturing the biologic. The composition of matter patents covering the biologic – typically viewed as the strongest form of protection because the ability to design around is hindered by the regulatory scheme – had already expired. In a future scenario where a composition of matter patent provides meaningful protection beyond the 12-year exclusivity period, I would expect settlements, and biosimilar launch dates, to reflect the strength of the composition of matter patent(s). That does not mean it will be uncommon to see early entry provisions allowing for biosimilar launch before expiration of all patents covering the biologic. To the contrary, it is highly likely that we will continue to see early entry provisions and related licenses granted to the biosimilar applicant, particularly because many biologics are covered by dozens of patents beyond composition of matter patents. I expect that the trend of settling patent litigation without cash payments – with the exception of anticipated litigation costs saved – that has emerged in small molecule brand-generic settlements after the

Supreme Court's decision in *FTC v. Actavis* – will carry over into biologic-biosimilar settlements. I also expect that no-AG [authorized generic] commitments, which had been common in brand-generic settlements, to be infrequent because the underlying rationale for such commitments – to give the first filed generic a true period of generic exclusivity – is not contemplated for biosimilar applicants under the BPCIA.

EB: Following up on the point about the *Actavis* decision, that is the case in which the Supreme Court found that reverse-payment agreements (colloquially referred to as "pay-for-delay") are subject to antitrust scrutiny. The FTC conducted an analysis of generic patent settlement agreements following the *Actavis* decision. According to that analysis, following *Actavis*: 1) potentially unlawful reverse-payment settlement agreements declined by 50%; 2) there was a big increase (to more than 80%) in settlement agreements that did not involve any payment to the generic company; and 3) there was a decline in commitments by the brand company not to launch an authorized generic. We may see similar trends in biosimilar patent agreements going forward.

JS: Those are interesting numbers, Elaine. I also think the pending class actions challenging Abbvie's settlements with several biosimilar firms, which Elaine touched on when discussing patent thickets, could play a significant role in shaping future biosimilar settlements. The patent settlements at issue allow biosimilar firms to enter European markets immediately but prohibit them from entering U.S. markets until 2023. The plaintiffs argue, among other things, that the settlements constitute illegal "pay-for-delay" agreements. Not only could this case answer whether *Actavis* principles apply in the biosimilar context, but could also determine the extent to which valuable non-cash consideration *(e.g.,* permitting biosimilar manufacturers to immediately enter European markets in exchange for delaying entry into the U.S. market) can constitute the type of "large and unjustified" payments that the Supreme Court warned against in *Actavis*.

SP: Under the Hatch-Waxman regime, many settlements contained a "most favored nations" clause allowing later filers to have the same entry date as earlier non-first filers or six months after the first filer(s). In the biosimilars space, I expect that reference product sponsors will be less willing to provide MFN clauses to delay and control price erosion and an applicant's ability to capture significant market share. We have already seen a glimpse of this strategy in settlements for Humira (adalimumab) biosimilar where the entry dates for biosimilar applicants are staggered. Under the current settlements, as Joy noted above, Amgen's entry date is January 31, 2023, Samsung Bioepsis enters on June 30, 2023, Mylan enters on July 31, 2023, Fresenius Kabi and Sandoz enter on September 30, 2023, Momenta and Pfizer enter on November 20, 2023 and Coherus enters on December 15, 2023.

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>
> *Elaine Herrmann Blais*

JB: When settling cases, lawyers are often challenged to "think outside the box." This commonly means that if the parties are deadlocked about the amount of money that should be paid, a settlement might still be achievable if the parties find another manner of providing consideration, such as agreeing to ongoing business dealings. However, in the context of Hatch-Waxman settlements, "thinking outside the box" can lead to antitrust risk.

JS: Can you give us some examples, Jon?

JB: Sure. Some settlements have involved the simultaneous resolution of multiple lawsuits involving multiple products. These kinds of attempts at global peace have an obvious advantage in reducing litigation risk, litigation expense, and burdens on the court – but antitrust plaintiffs have responded to some of these settlements by alleging that the settlement relating to Product A was a sham, a secret payment that induced the generic to improperly agree to delay the launch of a generic alternative to Product B. Regardless of whether this type of contention has merit, such fact-bound allegations tend to survive motions to dismiss, exposing the settling parties to expensive antitrust litigation and demands for 8 or 9 figure settlements.

To take another example, the Supreme Court in *Actavis* held that parties are allowed to include in Hatch-Waxman settlements payments that reflect "fair value for services." Some settlements, in addition to resolving litigation, have involved payments made in exchange for services such as manufacturing products or ingredients, or distributing an "authorized generic" version of a branded drug. However, "fair value" is in the eyes of the beholder. Numerous antitrust lawsuits allege that payments described by the settling parties as fair payment for services are actually shams designed to disguise improper pay-for-delay conspiracies. Indeed, a factual dispute of this nature was present in *Actavis* itself.

Similar incentives are in play regarding the settlement of patent lawsuits involving biologic products. There is commonly a strong, and appropriate, incentive to settle lawsuits. Creative settlement structures may facilitate settlement. However, creativity increases the risk of antitrust lawsuits. As a result, we will likely continue to see the trend of manufacturers looking for new ways to resolve expensive and risky litigation, and reshaping their settlement strategies as antitrust case law evolves to show which kinds of settlement terms are safe and which are likely to lead to follow-on litigation.

JS: And given the inevitable scrutiny by the FTC and DOJ, as well as the courts, how do you see future biologic antitrust litigation settlements differing from brand-generic settlements? Let's hear from Kevin and Jon.

KO: A recent legislative update aligned governmental review of biologic-biosimilar settlements with an already existing procedure for brand-generic settlements. The legislative update requires the parties to file with the FTC and DOJ any settlement agreement entered into after the biosimilar applicant has provided its statement required by Paragraph 3(B)(ii)(I) to the reference product sponsor. With respect to this antitrust scrutiny, biologic-biosimilar settlements may have a higher threshold for anticipated litigation costs saved

GOODWIN

Elaine Herrmann Blais
Partner, Goodwin

Schiff Hardin

Sailesh (Sal) Patel
Partner, Schiff Hardin LLP

given the more complex nature of the BPCIA litigation scheme compared to the Hatch-Waxman scheme. Moreover, at least at the outset, price reductions for biosimilars have been less than price reductions for generics, so the potential anti-competitive impact of biologic-biosimilar settlements may be viewed to be less than that of brand-generic settlements.

JB: Two factors driving litigation generally, and pharmaceutical antitrust litigation in particular, are money and uncertainty. From the manufacturers' perspective, the cost of developing innovative new therapies is immense, and for a blockbuster product, the rewards can be even greater. There is as a result a strong incentive to take all legal steps to preserve the rewards for successful innovation. Determining what strategies are legal, however, can be difficult. Recall that before the Supreme Court's *Actavis* decision, most courts adjudicating allegations of "pay-for-delay" held that payments were lawful so long as the delay did not exceed the scope of the patent.

Even today, the lower courts are still engaged in the process of sorting out what kinds of consideration can constitute a payment, when payments are sufficiently large to justify antitrust scrutiny, what justifications are cognizable, and other questions relating to the lawfulness of settlement agreements. The manufacturers entering settlement agreements, however, of course do so before the propriety of the agreement has been adjudicated. Given the complexity (and the often ambiguous nature) of both Hatch-Waxman and antitrust jurisprudence, manufacturers have entered into any number of settlements that may have seemed unremarkable when entered but resulted in costly antitrust suits.

JS: As you have mentioned in our discussions, Jon, private lawyers bring far more litigation than the FTC or DOJ. Do you believe the plaintiffs' class action bar is in sync with the government?

JB: From the perspective of the plaintiffs' class action bar, similar business considerations are in play. Plaintiffs commonly claim that their damages are measured in the billions of dollars in antitrust cases related to major pharmaceutical products. These potential rewards make it rational for plaintiffs to raise and aggressively litigate claims where the legal or factual predicate is unclear. The laws surrounding biologic products, like the laws surrounding small-molecule generic products, involve no shortage of complexity and uncertainty. The exact form biologic settlements take will likely differ from the form taken by prior Hatch-Waxman settlements, and indeed the exact means used to settle future Hatch-Waxman cases will likely surprise us as well. But the underlying dynamics are likely to continue to generate both creative settlements and creative antitrust claims.

JS: Let's pivot back to the patent issues for a moment. In January 2019, the USPTO released additional revised guidelines to ensure application of the two-step *Alice/Mayo* test in "a manner that produces reasonably consistent and predictable results." How will the 2019 USPTO guidance revisions impact biosimilars?

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>
> *Sal Patel*

SP: The 2019 guidance on patent eligibility aims to harmonize the application of section 101 among examiners, which will likely make patent examiners more lenient in allowing patents. On its face, the guidance is limited to a discussion of three groupings of abstract ideas—mathematical concepts, certain methods of organizing human activity, and mental processes—and does not directly address laws of nature or natural phenomena (including products of nature), which would have more direct implications to biologics. Indeed, the guidance says that it "does not change the type of claim limitations that are considered to recite a law of nature or natural phenomenon."

However, this guidance along with the proposed amendments to section 101 discussed at the recent Senate hearing show an increasing trend towards reducing (or even potentially eliminating) the impact of the Supreme Court *Alice* decision on defeating patents. If this trend continues, we can expect an expansion of patent eligible products of nature, and methods of producing biologics or methods of treatment using natural phenomenon. This would serve to increase the size and scope of patent thickets surrounding many reference products in the biologics space, heightening the barrier to entry for biosimilar products in the United States.

KO: The USPTO has been continually updating its guidelines in response to Federal Circuit decisions attempting to apply the Supreme Court's framework for evaluating patent eligibility under *Alice*, *Myriad*, and *Mayo*. While the recent evolution of the patent eligibility jurisprudence has generated a substantial amount of uncertainty and unpredictability, it appears that the pendulum is swinging back toward eligibility, at least for certain types of claims. In particular, claims structured as a method of treatment – even those encompassing a diagnostic step – have been granted by the USPTO and upheld by the Federal Circuit. For example, in the *Vanda* case, which has been appealed to the Supreme Court, the claims are directed to a method for treating a schizophrenic patient with one amount of a compound if the patient has a poor metabolizer genotype and a different amount of the compound if the patient does not have the poor metabolizer genotype. The USPTO's most recent guidance indicates that such method of treatment claims may be considered a "practical application" of a natural relationship.

While method of treatment claims can provide a barrier to biosimilar commercialization, such claims may also be vulnerable to design around. For example, as in the generic drug context, a biosimilar applicant could pursue a "skinny label" that does not include the particular indication covered by the reference product sponsor's method of treatment claims. In fact, there is no requirement that a biosimilar applicant seek approval for all approved indications. Also, to the

extent that such method of treatment claims is tied to a particular biomarker, it may be possible for the biosimilar applicant to craft its label to avoid direct infringement. However, such labeling may only delay a suit until after launch when a biologic may proceed against the carved out indications under a theory of induced infringement. In these circumstances, the biosimilar applicant would be wise to also refrain from making statements that may encourage off-label use in its marketing and informational material.

One important distinction between small molecule generic drugs and biosimilars is a greater opportunity for the biosimilar applicant to generate innovations, for example, around new formulations or methods of manufacturing. Thus, a biosimilar applicant should consider pursuing patents on its own inventions to provide a tool to protect its research and investment against other biosimilar competitors. Moreover, a thorough, ongoing freedom to operate investigation should include an assessment of patents owned or licensed by other biosimilar applicants.

EB: In addition to the PTO guidance, there has also been a fair amount of legislative activity on the 101 issue. As Sal mentioned, Senators Chris Coons and Thom Tillis in May released a draft patent reform bill directed at Section 101 issues. The Senators also held three days of hearings on the issue in June. The proposed legislation would introduce a definition of the term "useful," which already appears in Section 101, to mean: "any invention or discovery that provides specific and practical utility in any field of technology through human intervention."

This would create a new standard for determining whether a patent is directed toward eligible subject matter, and is intended to abrogate the prior case law establishing exceptions to patent eligible subject matter under Section 101, such as "abstract ideas," "laws of nature," or "natural phenomena."

The legislative proposal also stated that Section 101 eligibility should be determined without regard to whether individual claims limitations were "well known, conventional, or routine." This would abrogate the second step of the *Alice/Mayo* test established by the Supreme Court, which requires courts to look to individual limitations of a claim to determine patent eligibility and consider whether or not those steps were conventional or known in the relevant art.

Whether such a proposal, if enacted, would actually change the outcome of any given case remains to be seen. As Senators Tillis and Coons said in a post-hearing statement, the intent of their proposal is to change the legal standard, but not necessarily what would have been the outcome in prior cases.

JS: **Within the biopharma industry, the inter partes review (IPR) has been one of the most formidable vehicles for challenging the patentability of one or more claims in a U.S. patent. Given the use of patent thickets as a barrier to biosimilar market entry, is there an IPR strategy that might speed biosimilars to market?**

KO: As a vehicle to challenge a blocking patent on prior art grounds, IPR provides a petitioner with certain advantages over district court litigation. For example, the challenged patent does not have a presumption of validity that it would have in district court and the burden for proving invalidity in an IPR is lower than in district court litigation. In addition, there is no standing requirement in IPR, which allows for a petitioner to challenge a patent even prior to product launch or the initiation of district court litigation, including litigation under the BPCIA. As a practical matter, however, a biosimilar applicant may wish to first narrow the list of relevant patents during the initial stages of the BPCIA patent dance before proceeding with its IPR strategy.

Despite the apparent attractiveness of IPR as a vehicle to challenge blocking patents, a biosimilar applicant should proceed with diligence, especially in light of the estoppel provision that is triggered by failure to invalidate the patent claims. The estoppel provision forecloses a losing IPR petitioner from later asserting in district court litigation or ITC proceedings any invalidity ground that it raised, or reasonably could have raised, during the IPR. In practice, a petitioner is estopped from later asserting any prior art grounds that were raised and substantively considered by the PTAB in a written decision; conversely, a petitioner is not estopped from asserting prior art grounds included in the petition but not substantively considered by the PTAB *(i.e.,* where the PTAB denied institution).

While the Federal Circuit has not explicitly held that a petitioner is estopped from asserting non-petitioned grounds in later proceedings, several district courts are now interpreting the clause "reasonably could have raised" as including non-petitioned grounds. Thus, a biosimilar applicant should be wary of withholding certain prior art references during an IPR in an effort to avoid estoppel. A biosimilar applicant that is considering challenging the reference product sponsor's patent(s) in an IPR should thoroughly search the prior art and carefully select the most pertinent references. If alternative invalidity positions are identified, petitioners should consider including multiple grounds in its petition – or even simultaneously filing multiple petitions – to present each alternative position. The biosimilar applicant should carefully evaluate non-prior art invalidity positions *(e.g.,* under Section 112) that are not subject to the estoppel provision to ensure that it has an option to challenge patent validity in a district court, should its IPR be unsuccessful. Of course, further decisions from the PTAB and Federal Circuit will help to refine – and potentially revamp – the ideal IPR strategy for a biosimilar applicant.

JS: **Some of you raised the issue of education as another potential barrier to entry for biosimilars. Ali and Sal, do you believe that there is an insufficient amount of education on the safety and efficacy of biosimilars?**

AA: Certainly, limited understanding across all stakeholders continues to be an issue. Physicians and patients generally ask for robust clinical data in reviewing new drugs and, without such data, they may question the quality and safety of biosimilars. Reference manufacturers may have decades of history that not only looks at relapse rates, but also long-term survival and other significant endpoints associated with their products. The goal of a biosimilar program is not to independently establish safety and effectiveness for each condition of use. Rather, the goal is to demonstrate biosimilarity through an extensive analytical characterization and a targeted clinical program designed to assess for clinically meaningful differences, if they exist. Biosimilar manufacturers generally rely on well-established scientific principles such as extrapolation of data across indications to forego conducting clinical trials in each indication.

Nevertheless, certain stakeholders may be skeptical of the efficacy of a biosimilar without clinical studies for each indication, despite the fact that FDA has allowed the approval of the biosimilar product without necessitating additional clinical data. The FDA is taking and should continue to reinforce measures to help inform these stakeholders in an attempt to clear confusion and

avoid such misperceptions. Unfortunately, reference sponsors create confusion about the safety and effectiveness of biosimilars which undermine consumer confidence in biosimilars. By way of example, one reference sponsor's patient literature characterizes biosimilars as "similar" rather than "highly similar." Yet another reference sponsor's direct-to-consumer advertising suggests risks by switching drugs *(e.g.,* from a reference product to a biosimilar).

JS: Agreed. Not only do stakeholders currently have limited understanding of biosimilars, but they are also unlikely to develop this understanding in the near future absent a change in conduct by biologic manufacturers. As discussed above, pricing and contracting strategies by biologic manufacturers have caused a significant portion of insurance companies to restrict coverage of biosimilars. This, in turn, has prevented many healthcare providers from even stocking biosimilars. Stakeholders, particularly physicians and insured patients, have little incentive to spend time developing an understanding of biosimilars that are neither covered by insurance nor available in many hospitals.

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>
> *Joy M. Sidhwa*

SP: I know that biosimilar manufacturers continue to invest substantial resources in focusing on the fact that an FDA-approved biosimilar must have no clinically meaningful differences from the reference product. In addition, biosimilar manufacturers are investing in patient support programs to personalize for patients, physicians, and pharmacies to quickly and conveniently access the information and support they need, when they need it, through services such as helplines, apps, emails, and educational websites. The FDA and HHS could also take a more active role in providing educational resources. In the UK, the NHS provides educational resources regarding biosimilars and switching from a reference product.

JS: I want to thank you all for your participation. This has been a riveting discussion - one that I think we will revisit over the next year or two. It would also be remiss of me if I did not thank MoginRubin associate Timothy LaComb, who was instrumental in researching and assembling this piece.

Ali Ahmed
Senior Vice President
Fresenius Kabi, USA

Ali Ahmed leads biosimilar strategy and commercialization, in the United States, for Fresenius, a Top 40 global pharmaceutical company. He has a Bachelor of Science in Chemical Engineering from Washington University in St. Louis and a Juris Doctorate from The George Washington University in Washington D.C.

Elaine Herrmann Blais
Partner & Head of Litigation for Boston
Goodwin

Elaine Herrmann Blais focuses her law practice on intellectual property litigation, particularly with respect to patent litigation for the life sciences industry. Ms. Blais is the co-founder and editor of the firm's blog, www.bigmoleculewatch.com, which is dedicated to providing resources and observations through Goodwin's active watch of the world of biologics, biosimilars and the Biologics Price Competition and Innovation Act (BPCIA). Elaine has a B.A. in Psychology from Allegheny College and a J.D. from The Ohio State University, College of Law.

Sailesh Patel
Partner
Schiff Hardin LLP

Sal Patel is co-leader of Schiff Hardin's Intellectual Property Group and the Hatch-Waxman and Biosimilars practice. With a background in chemical and biomedical engineering, he is familiar with the language of the pharmaceutical and life sciences industries. Sal is a seasoned trial attorney known for implementing creative and scientifically sound arguments for his clients. He has a B.S. in Chemical Engineering from Northwestern University in Illinois and a J.D. from Boston College Law School.

Jonathan Berman
Partner
Jones Day

Jon Berman has over 25 years of experience in antitrust and other complex litigation. His practice focuses on the interplay between civil litigation and the laws administered by the Food and Drug Administration. He graduated from Harvard College and Columbia Law School.

Joy M. Sidhwa
Senior Attorney
MoginRubin LLP

Joy Sidhwa concentrates on antitrust and other complex litigation for MoginRubin and leads the document discovery team. Ms. Sidhwa received her Bachelor of Science in Biopsychology, Cognition, and Neuroscience from the University of Michigan in Ann Arbor and her J.D. from California Western School of Law in San Diego.

Kevin A. O'Connor, Ph.D.
Partner
Neal Gerber Eisenberg

Kevin O'Connor represents his clients in all aspects of patent law, including due diligence investigations for business transactions, strategic patent counseling and patent portfolio management, and opinion preparation, focusing his practice primarily on the biotechnological, pharmaceutical, and medical device industries. Kevin received his Ph.D. in Neuroscience from the University of Colorado and his J.D. from the Chicago-Kent College of Law.