# Re-Engineering

## THE PHARMA GENERAL COUNSEL ROLE

by Julie Goldberg

There has perhaps never been a time when the general counsel's (GC) role was anything less than crucial and challenging. But in recent years, the GC has been transformed from a tactical legal practitioner to a true strategic business partner, aiding the CEO in the most critical decisions the organization makes. Nowhere is this more evident than in the highly competitive and heavily regulated pharmaceutical industry.

Today's general counsel interfaces with and guides the CEO in his or her vision for the company, and has deep relationships with finance, enterprise risk management, human resources and the board of directors. The GC must help fashion long-term strategy that supports the CEO's vision for growth, while maintaining vigilance to ensure regulatory compliance and protect the reputation of the organization.

The emotionally and politically charged arena in which biopharmaceutical companies operate heightens the strategic importance of the general counsel role. On one hand, drug companies are being scrutinized more closely than ever before by regulatory bodies such as the Food and Drug Administration (FDA) and the Securities and Exchange Commission (SEC), not to mention legislators, advocacy groups and an increasingly health-conscious public. At the same time, industry consolidation and shareholders' growth expectations have prompted an unprecedented level of deal-making, from mergers and acquisitions to licensing agreements, all of which require input from the GC.

The general counsel plays a critical role in both of these areas. He or she must still be the consummate lawyer, drafting agreements and keeping the organization within the letter of the law. Indeed, the passage of Sarbanes-Oxley and the increasingly litigious regulatory environment make the GC's traditional position more important than ever. But the GC is also increasingly called upon to negotiate, structure and pass judgment on licensing agreements and other deals. In addition, the job also has grown to encompass risk management and building the business.

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"At the same time that general counsels are asked to be more than just lawyers, I think there's been a counterweight to that," says George Lykos, chief legal officer and secretary of the Bayer Corporation. "You need to be ever mindful of being a lawyer as well as a strategic partner," he says. "We're being asked to burn both ends of the candle."

## A Seat at the Table

The emergence of the biotechnology industry in the 1980s marked a pivotal point in the evolution of the general counsel's role in business strategy. For a century previous, pharmaceutical companies had leveraged their proprietary libraries of chemical compounds, and rarely looked outside their own laboratories. But that cozy world was turned upside down by the biotech paradigm, which created clones of naturally occurring proteins using the new science of recombinant DNA. Suddenly it was possible to produce unlimited amounts of essential hormones, such as insulin, using the tools of biotechnology.

Lacking the tools and the expertise to duplicate these protein clones, the large pharmaceutical companies scrambled to license the fruits of biotech

from pioneering companies like Amgen, Genentech, Cetus and Chiron. It was, in some ways, a perfect pairing. The biotech companies needed cash, and the endorsement that came from partnering with an industry heavyweight such as Merck or Pfizer, and the big pharmaceutical companies needed a new source of novel compounds to augment their internal drug discovery programs. But the licensing deals were inevitably complicated by the large companies' concerns about overpaying and the biotech companies' reluctance to license away their futures.

The role of the general counsel came to the fore in 1990, when Roche Holdings, based in Switzerland, purchased a majority stake in Genentech. It was an unusual deal, featuring both a put and a call option, which effectively limited the trading range of Genentech shares for years to come, allowing the company to spend freely on research and development without being punished by Wall Street. John P. McLaughlin, then Genentech's GC, was one of just four of the biotech company's executives at the negotiating table.

"I played a combination role," recalls Mr. McLaughlin, who is now President and CEO of Corgentech Inc., which develops drugs for cardiovascular disease, cancer and inflammatory disease. "It was a mixture of 'what's the best deal you can strike' negotiating, but also giving advice as to how to structure a deal—and we put in some pretty novel structures. We were trying to build in some protection for our shareholders and we were pretty clever. It's not just, 'here's a legal structure'—which is obviously important—but within the confines of what we can do legally, here are some things that can further our business strategy."

Large pharmaceutical companies are under more pressure than ever to fill their pipelines, and to show investors there will be a steady stream of new drugs getting approved and coming to market. That pressure leads them to do more deals with biotech and specialty pharmaceutical companies. At the same time, the public equity markets have grown reluctant to finance early-stage biotech efforts, making these companies more willing to partner or be acquired.

"We've all been roundly accused of having weak pipelines, which accounts for so much interest in the biotech companies, and their stocks trading at unreal multiples," says Jim Elrod, general counsel at King Pharmaceuticals, Inc. "Not only does that put a lot more attention on the transaction side, but the earlier you do a transaction, the riskier it is, which only puts more pressure on the legal and

due diligence aspects. One of the GC's most important roles is to play a check and balance against the business guys, sometimes against the CEO or the CFO," he says. "There's got to be comfortable tension in order for this role to work the way it should."

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## From Tactics to Strategy

The movement from general counsel to the chief executive suite underscores the growing strategic importance of the GC's role. Cynthia Ladd, who reported to McLaughlin at Genentech and was later GC at Pharmacyclics, Inc., served from 2003 to 2005 as president and CEO of AGY Therapeutics Inc., which develops biotherapeutics for diseases of the central nervous system.

Large companies are also recognizing the strategic role of the general counsel. In February 2005, Pfizer promoted its general counsel, Jeff Kindler, to vice chairman and made him a member of its newly formed executive committee.

Despite her own career path, Ladd says that large pharmaceutical companies are actually more advanced in using the general counsel as a strategic partner than are smaller biotech companies.

"The reason is that CEOs in smaller companies tend not to understand what GCs can do for them," she says. "They tend to look for people who can draft their contracts, be in charge of Sarbanes-Oxley when they go public, and other things that are really tactical," she says. "They're also looking to not spend a lot of money, so they get a pretty junior lawyer."

But Ladd admits that she sees changes in the general counsel's role in companies large and small. "A lot of this is driven by the regulatory environment, both SEC and FDA. A CEO only has to sign a Sarbanes-Oxley certification one time to get a lot of religion," she says. "I also think that we have gotten to the point where there have been enough lawyers with very high profiles—think of Bill Neukom at Microsoft—that CEOs think 'maybe there's some value in these people that I didn't appreciate before.'"

Sarbanes-Oxley may have struck fear into the hearts of CEOs, but it has also moved general counsels into the boardroom, where they are expected to do more than simply ensure compliance.

"Sarbanes-Oxley created a different world of liability for directors, and a different level of scrutiny for responsible directors, where they're taking their role much more seriously and being much more involved in decisions, rather than leaning toward management on everything," says Stephen Rosenfield, general counsel at Tercica, Inc., which has developed IGF-1 (insulin-like growth factor-1) as a treatment for shortness in children who do not respond well to other drugs. "The board is really examining legal issues and wanting to get involved at a deeper level, and I think that's a good thing. It's good for the GC, too. You're involved in key decision-making and not siloed away as someone who's not participating."

If Sarbanes-Oxley created work for the general counsel on the financial side of the business, Merck's withdrawal of the pain reliever Vioxx—after it was shown to have caused cardiac deaths—has increased the GC's interaction with the FDA.

"We always had the tension between regulatory and product liability issues, but now you have a confluence of those," says Glenn Engelmann, general counsel and compliance officer for AstraZeneca. "As some of our competitors have seen, that gets played out on Capitol Hill. Post-Vioxx, the level of transparency the government is insisting on is much greater. That requires a certain awareness, and issues that once might have played out in private within the company are going to get played in public, so you have to go in with a different mindset."

Another factor that has moved general counsels closer to the CEO and the board is the growth of what some have called "regulation by litigation." The increased use of the Federal False Claims Act and the Medicare Fraud and Abuse statutes

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to punish drug companies for the aggressive marketing of their products has involved the GC in an area of decision-making that historically had little legal content. A provision in the law excludes companies found guilty from future Medicare or Medicaid payments, a particularly potent weapon for prosecutors.

James Sheham, general counsel at Novo Nordisk, says that false claims cases are the single biggest change he has seen in more than ten years in his position. "You have this problem of criminalizing conduct that in every other industry is not only not criminal but perfectly legal and acceptable," he says. "Because of the exclusion authority built into the law, companies will not take cases to court with a judge as an impartial mediator, so companies settle. Prosecutors don't give good guidance, but would appear to prefer to come after you after the fact."

General counsels in biopharmaceutical companies have always spent a significant percentage of their time on intellectual property (IP) issues, whether acquiring it or defending it. But GCs say that aspect of their role has changed as well, requiring a much more nuanced understanding of the relationship between IP and business strategy.

"In the past, many companies tended to look upon IP as a defensive measure, a basis for excluding others from competing in the market," says Bayer's Lykos. "That served a purpose for a while. But I've always considered that IP is far more than a way of occupying space. It has commercial value that can be leveraged. It can be traded, it can be licensed, it can be turned into something other than what it is. I think most pharmaceutical companies today have embraced the idea that

IP is far more than something that occupies a space in the universe."

At the same time, a strong defensive mindset remains important. "You have to assume that any successful product is going to be subject to multiple patent challenges," says Mr. Engelmann of AstraZeneca. "The generic industry is based on the quality of the lawyers and their ability to break patents. They're using IP offensively, and finding new theories to challenge patent property. So you really need to be thinking strategically about what kind of patent property you need to protect your products."

## An Ever-Expanding Role

Albert Halluin earned a place in biopharmaceutical history when he obtained a patent for a Cetus scientist's invention of polymerase chain reaction (PCR) technology, which ultimately garnered a Nobel Prize. Today, he still counsels companies on IP strategy, as senior counsel at Wilson Sonsini Goodrich & Rosati, a prominent Silicon Valley law firm, but he also sees the general counsel's role as an expanding one.

"Just about everything a company does today, the general counsel has to be commenting on," says Halluin. "FDA issues, HR, securities issues, all the deals, whether licensing, merger or acquisition, the GC has a hand in. You're finding today that the GC, whether inside or outside, is right at the CEO's side."

*Julie Goldberg, J.D.*
*is a Senior Client Partner in*
*Korn/Ferry International's New York*
*office and Co-Leader of the firm's*
*Legal Specialist Group.*

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