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Inequitable Conduct[i]

Judge Reyna, in an opinion by the Federal Circuit upheld a district court, decided that Apotex's patent was unenforceable due to inequitable conduct. The patent claimed a process for manufacturing tablets for treating high blood pressure and included a "reacting" step. To overcome prior art during prosecution, the inventor argued earlier processes did not include the claimed "reacting" step and submitted an expert declaration in support of this contention.

The Federal Circuit held clear and convincing evidence established that the inventor knew the earlier processes included the "reacting" step, concealed the knowledge from the USPTO, and misrepresented the prior art through the expert declaration and arguments during prosecution. The district court also found that Dr. Sherman withheld relevant prior art and submitted results of experiments that he never conducted. The district court observed that Dr. Sherman selectively displayed at trial a lack of memory and responsibility that led the court to conclude he was not a credible witness. The district court found that Dr. Sherman lied in the '556 patent application by including certain examples of experiments that were never conducted. In general, these are called prophetic examples and are distinguished from real example in the tense used – real examples in the past tense and prophetic examples in the present tense. The court noted that each example is written in the past tense as if it had occurred, but Dr. Sherman admitted at trial that the experiments were made up in his head (i.e., prophetic examples[ii]).

The misconduct was "but-for-material" because the USPTO would not have issued the patent but for the inventor withholding and affirmatively misrepresenting the prior art. Based on the overall pattern of misconduct, intent to deceive the USPTO was the "single most reasonable inference that could be drawn from the evidence."

Globalization of Layoffs[iii]
There are two sides to every story, and when it comes to pharmaceutical company layoffs, this is no exception. While we may understand the financial motivations behind management decisions that lead to job loss . . . whether it is to improve earnings per share, make a company more appealing or less appealing for a potential buyout or takeover, or to simply tighten the operating belt, the human side of layoffs is a hard pill to swallow. India-based Piramal Enterprises Ltd announced the company will be ending its early-stage development projects, but will continue its generic and contract research business. The company's subsidiary, Piramal Life Sciences, has about 400 scientists scattered around the globe. About 180 of its employees received an internal memo informing them of the plan and encouraging them to take early retirement or transfer to the company's generic medicine development and contract research units. The most strategic thing to do from the investor point of view, is to review the high-cost and long-gestation early-stage discovery business, and cut it out. No wonder, Piramal Enterprises' stock got a 4% boost, because investors like the lay off. Piramal Enterprises had agreed to develop a joint venture company with Navin Fluorine International to develop, manufacture and market specialty fluorochemicals.

Allergan announced 1,500 layoffs and there are actually more job cuts coming. There are more people who are going to be potentially impacted. One of Allergan's values is "People + Passion." It states, "We succeed primarily through our people, whose talent brings quality to our work and whose passion brings commitment—not just from processes and structures alone." But, the layoffs affect individuals at all levels, from the high school graduate to those who have advanced degrees; devoted employees who were counting on a successful and long future with the company, and most importantly families who become disrupted or destitute[iv].

Executive Pay[v]
Over the past four years, compensation for the top five executives at each of 2nd tier drug makers Actavis, Allergan, Hospira, Momenta Pharmaceuticals, Mylan Laboratories, Teva Pharmaceuticals and Theravance, averaged about $20 million a year, with a compounded annual growth rate of 3% – and 43%

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of total executive team compensation went to the CEO. In 2013, executive team compensation ranged from $39 million at Mylan to $5 million at Theravance. Overall, compensation for top management averaged $20 million compared with $39 million among large cap drug makers. Actavis created the most value to shareholders in the past five years while maintaining mid-range exec compensation packages at about $20 million. Long-term incentive pay as a percentage of the total pay package stabilized after growing for several years and even declined a bit for CEO's, while growing for other officers. The median CEO long-term incentive share of compensation remained at 67%, while the median for the other execs dropped to 61%. All of the drug makers now require the exec teams to have a meaningful level of ownership and the figure has been increasing – three to six times base salary for the CEO, and one to five times for other execs. Beneficial ownership averaged 1% to 2% of equity, but this is larger in the smaller companies – 8.1% at Momenta and 3.6% at Theravance.[vi]

Source: The primary sources cited above, New York Times (NYT), Washington Post (WP), Mercury News, Bayarea.com, Chicago Tribune, USA Today, Intellihealthnews, Deccan Chronicle (DC), the Hindu, Hindustan Times, Times of India, AP, Reuters, AFP, womenfitness.net, about.com, mondaq.com, etc.

Om! Asatoma Sadgamaya, Tamasoma Jyotirgamaya, Mrityorma Amritamgamaya, Om Shantih, Shantih, Shantih!
(Aum! Lead the world from wrong path to the right path, from ignorance to knowledge, from mortality to immortality, and peace!)

[i] Read more at http://www.cafc.uscourts.gov/images/stories/opinions-orders/13-1674.Opinion.8-13-2014.1.PDF

[ii] Constructive reduction to practice is writing down ideas that can be practiced. Prophetic examples are constructive reduction to practice and are a common practice. Constructive reduction to practice requires compliance with 35 U.S.C. 112(a) or pre-AIA 35 U.S.C. 112, first paragraph. Read more at http://www.uspto.gov/web/offices/pac/mpep/s2138.html

[iii] Read more at http://www.biospace.com/News/piramal-life-sciences-exits-drug-discovery/344587/source=TopBreaking

[iv] Read more at http://www.biospace.com/News/allergan-inc-layoffs-employees-tell-their-side-of/341040

[v] Read more at http://blogs.wsj.com/pharmalot/2014/08/27/worth-the-money-assessing-executive-pay-at-specialty-drug-makers/

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