

PAINTING THE SWAN BLACK: ON THE ART OF RE-INVENTING INVENTIONS

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The author argues that it is important to distinguish between genuinely innovative 'Black Swans', and swans that are painted black, referring to the increasingly common practice of making cosmetic or insignificant modifications to existing innovations in order to obtain or extend patent protection. This, the author argues, is especially significant in the pharmaceutical sector, since experience has shown beyond any doubt that a substantial portion of its revenues emanate from incremental inventions as opposed to Black Swans. This is not likely to change either, given the steadily widening gulf between investment in and return from research and development in the industry. The author goes on to identify a concrete mechanism that is conducive to this process of weeding out Black Swans from the impostors - pre-grant opposition strategy, and argues that its merits far outweigh any possible delay in the process of the grant of patents.

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I. INTRODUCTION

To many of us, a black swan defines an aberration. It is a strikingly odd (by some accounts, extremely ugly), attention-grabbing, feathered creature that

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combines the gracefulness of a swan and the macabre of the colour black. A black swan represents an extremely rare thing. The sighting of the black swan for the first time in newly discovered Australia, centuries ago, overturned a general statement derived from thousands of sightings of swans in the Old World – that all swans were white. Until the discovery of what was already there down under, the existence of a black swan was, to say the least, highly unexpected. It was much like a white crow whose hypothetical existence was confined to unbelievable stories and entertaining folklore. The idea of a black swan in popular thought has been linked with unpredictable, extreme impact events that lie outside the realm of regular expectation.

Black Swans have three defining characteristics - rarity, extreme impact and retrospective predictability.¹ Almost everything of some importance around us will qualify for a Black Swan. 9/11 was an event which shared Black Swan traits. The same could be said about the unexpected rise of Google and the fall of the mighty Soviet Union. The cellular phone, which is now ubiquitous, was once a Black Swan. The combination of low predictability and large impact makes the Black Swan a desirable business outcome. Black Swans exist in all businesses. In fact, businesses are constantly looking out for Black Swans. It could be the "next big thing", "the killer innovation" or the "wonder drug" which is new, non-obvious and cannot be conceived by others. As the Black Swan logic makes what you do not know far more relevant than what you do, the industry is quick in identifying a Black Swan and quicker in protecting it. In the field of technology, Black Swan innovations are protected by means of patents.

II. THE INNOVATION PROCESS

Peter Drucker, one of the foremost thinkers on management, characterised innovation as the effort to create purposeful, focused change in an enterprise's economic or social potential.² Innovation refers to the process of bringing out new inventions. For the purposes of patent law, which is concerned with inventions, technological innovation can be broadly classified into two categories - radical and incremental innovations. All innovations lie between these two extremes. Much of the technological advancements that we see around us have been commercialised through a clever mix of radical and incremental innovations. The life cycle of an

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1. N.N. Taleb, *THE BLACK SWAN: THE IMPACT OF THE HIGHLY IMPROBABLE* (New York: Random House, 2007).
 2. P.F. Drucker, *The Discipline of Innovation*, 76(6) HARV. BUS. REV. 149-57 (1998) available at http://www.businessweek.com/magazine/content/04_04/b3867097_mz017.htm.

innovative product begins as a radical innovation and continues through a number of incremental innovations.

Take for instance the development of 3M's innovative product, Post-it. Post-it, when first developed, was so radical an innovation that 3M had problems in marketing it. One can understand the astonishment of the stationery shoppers of the 1970s who were curiously greeted by a little yellow rectangular block of sticky papers. Once the radical innovation found acceptance in the market, 3M was quick enough to develop Post-it with a series of incremental innovations like colour-coded Post-it and the Post-it Highlighter.

Disposable diapers have also followed more or less the same cycle. What began as a replacement for traditional cloth-woven diapers, disposable diapers have come a long way in handling some of the messy problems of infancy. The commercial war between two pioneering companies, P&G and Kimberly-Clark, saw this radical innovation being constantly upgraded through a series of incremental innovations – 'boy' diapers and 'girl' diapers (which incidentally had nothing to do with identifying the gender of its users), diapers with Velcro, elastic and cloth-feel as well as light-weight and scented diapers which have a remarkable ability to camouflage unpleasantness when stuff happens.

Apple's iPod also went through the pangs of radical-incremental shift while growing up to be one of the most sought after technological gadgets of all time. The truly radical iPod had to be supported by the iPod mini which was an incremental innovation necessitated by the flooding of the market with cheap, lower-end copied versions of the iPod.

III. BLACK SWAN INNOVATIONS

Radical innovations are very much like the Black Swans – outsiders which stand outside our normal expectations. Radical innovations are truly remarkable, extremely rare and highly unpredictable – the iPods and the Post-its of every industry. Due to the predominant reliance on science and technology, Black Swans are critical for the survival of the pharmaceutical industry. The Black Swans of the pharmaceutical industry are better known as "Blockbusters", for their ability to generate sales of over a billion dollars a year. Quite rightly, the industry is looking for radical Black Swans, for the invention of one such can make up for the huge amounts a pharmaceutical company invests in R&D.

A. Serendipitous Black Swans

Way back in 1953, when researchers at 3M were developing a rubbery material for jet aircraft fuel lines, something surprising happened when a few drops of the research material accidentally spilled on a researcher's canvas tennis shoe. The material was so stubborn that it could not be wiped off the shoe. Instead of worrying over the damage caused to the shoe, the researchers at 3M smartly concluded that they had stumbled upon a material that could repel both water and oil. It took the genius of the people at 3M to develop this serendipitous discovery into a ubiquitous house-hold product used as a stain repellent and soil-remover, known to millions solely by its trade name – Scotchgard.³

Every serendipitous discovery qualifies as a radical or Black Swan Innovation. Serendipitous discoveries are common in all industries. It is often said that chance favours the prepared mind to notice when something does not go as expected, and to make sense of a stray event. As an industry built on a patent-based pharmaceutical development process, pharmaceuticals rely overly on 'unexpected and surprising effect' in patenting their products. Some significant discoveries in the pharmaceutical industry have been a result of observing the unexpected. Penicillin was discovered serendipitously. The same can be said about Pfizer's anti-impotence drug, Viagra (sildenafil citrate), which was initially used for treating hypertension and angina pectoris. Minoxidil's hair growing properties were noticed fortuitously while treating some bald patients for hypertension. The anaesthetic use of nitrous oxide (laughing gas) and ether were discovered accidentally. Apart from thrilling researchers with the joy of the unexpected, serendipitous discoveries also stand as testimonies to the unpredictable and inconsistent manner in which innovation occurs in many industries. However, the radical innovations in any industry have been few and far between. It is the incremental innovations that dominate the industry, more so in the pharmaceutical industry, where incremental innovations dominate radical innovations.

B. Incremental Innovation in Pharmaceuticals

Incremental innovations are minor changes and developments made to a radical innovation. It is common industrial practice to invent a radical innovation and develop it further incrementally. Incremental innovations are critical for the

3. Though Scotchguard was sold in 1956, it was in 1971 that the inventors, Patsy Sherman and Samuel Smith, obtained U.S. patent No. 3,574,791 'Block and Graft copolymers containing Water-solvatable polar groups and flouroaliphatic groups', for the method for treating carpets with Scotchgard. See Tony Davila et al, *Making Innovation Work – How to Manage it, Measure It and Profit from it* 130-31 (Pennsylvania: Wharton School Publishing 2006).

development of a product. The pharmaceutical industry has witnessed the practice of manufacturing versions of known drugs, known popularly as "me too" drugs. "Me too" drugs are incarnations of incremental innovation. Though they are mere versions of known drugs, they are marketed and protected like radical innovations. Often they are sold as high-priced editions of existing drugs, claiming some incremental advantage over what is already there. One of the best industry examples of a "me too" drug replacing a radical drug was witnessed in the market substitution of AstraZeneca's Nexium (esomeprazole) which successfully replaced Prilosec, the original purple pill.⁴ Nexium is derived from Prilosec which contains a racemic mixture of the D- and L- forms (isomers) of omeprazole. Nexium contains only one of the isomers. "Me too" drugs are also seen in statins, a kind of drug which lowers the level of cholesterol in the blood. Merck's Mevacor was the original statin, which was released in the market in 1987. Today, the market is filled with five more statins – Lipitor, Zocor, Pravachol, Lescol and Crestor – all manufactured by leading pharmaceutical companies. Ironically, Mevacor is not the best-selling statin. That honour goes to a me-too version of Mevacor, Pfizer's Lipitor whose annual sales exceed US \$13 billion.

IV. THE SEARCH FOR "BLOCKBUSTERS"

The pharmaceutical industry has been looking out for blockbusters. Blockbusters mean easy profit. The lure of huge pay-offs has enticed the industry to look out for potential blockbuster drugs. Lipitor earns Pfizer annual revenue in excess of US \$13 billion. AstraZeneca's Prilosec (used for the treatment of heartburn) earned US \$6 billion in 2001, the year in which its patent expired.

In no other field of technology does innovation play a more significant role than in the pharmaceutical sector. Empirical research has repeatedly demonstrated the importance of innovation and the need to protect these innovations in the pharmaceutical industry. Due to the unique positioning of the pharmaceutical industry, three factors affect the way in which the industry operates. *First*, the high costs of R&D have resulted in expensive drugs - drugs which need more than a billion dollars to develop. *Secondly*, it is relatively easy to duplicate these drugs by reverse engineering, as pharmaceuticals are chemicals used in the treatment of ailments and diseases and are as such susceptible to all the technical risks chemical compounds are exposed to. *Thirdly*, the indispensability of public health and the willingness of the consuming public to pay any price for the medicines have made the pharmaceutical industry a key player in seeking patents. The innovative

4. See <http://www.purplepill.com/about-nexium/>.

strength of the pharmaceutical industry can therefore not be underestimated. The impact of blockbuster drugs, drugs whose annual turnover are in billions, symbolise the importance of innovation in the pharmaceutical sector.

Despite the huge investments made by the pharmaceutical industry in R&D, the output of innovative drugs has been few and far between. The real sources of innovation have been academic institutions, small biotech companies and publicly funded research organisations. Some of the best-selling drugs in the industry have either originated or benefited from publicly funded research. For instance, AZT, the first AIDS drug, was developed by the National Cancer Institute and Duke University and later licensed to GSK. Taxol (paclitaxel), a leading cancer drug, was developed by the National Cancer Institute and Florida State University and later licensed to Bristol-Myers Squibb. Amgen's Epogen was developed by the University of Chicago and the University of Columbia. Novartis' Gleevec benefited from the research done by NIH-funded university researchers. The above illustrations are representative of how innovation happens in the pharmaceutical industry.

V. RE-INVENTING DRUGS

Aspirin changed many things for the pharmaceutical industry. When acetylsalicylic acid was discovered in 19th century, nothing significant happened till Bayer skilfully marketed the drug into a bestseller. Aspirin soon lost out to other analgesics like Paracetamol and Ibuprofen. The latter part of the 20th century witnessed the resurgence of the drug. Aspirin was reinvented when blood-thinning properties were discovered, thereby increasing the demand of the old drug. Discoveries such as these have shifted the focus of the industry from inventing new drugs to discovering new uses of known drugs and to lobbying for patent protection for such new uses.

The pharmaceutical industry has been playing it safe when it comes to huge investments in R&D. There is a great focus in the industry on new uses of known substances. The most spectacular example is Pfizer's anti-impotence drug Viagra (Sildenafil citrate), which was originally developed as a cardiovascular drug. Pfizer applied the drug for a new use to combat the problem of erectile dysfunction which made the drug a best-seller. Despite the world-renowned popularity of the drug, the drug does not enjoy patent protection in many jurisdictions. It does not enjoy patent protection in the UK, China and India, to name a few. This is due to the fact that the national jurisdictions have provisions in their law by which a new use of a known compound is treated as obvious and lacking inventive steps. The novelty is confined to novelty of use. Despite the restrictions on obviousness and

some special laws which oppose the grant of patents for new uses of known substances (like s. 3(d) of the Indian Patents Act 1970), pharmaceutical companies continue to place heavy reliance on developing new forms and new uses of old and known drugs. It is no surprise that the world's largest pharmaceutical company, Pfizer, has as its future growth plan the examination of drug targets whose role in diseases is already well established.⁵

VI. RELIANCE ON INCREMENTAL INNOVATION

The overwhelming reliance on incremental innovation by the pharmaceutical industry is attributable largely to the industry's need to play safe. Johnson & Johnson opted for such a strategy by relying on line extensions, cost-cutting and acquisitions to hold off the competition as there were only a few new drugs in the pipeline in the short term.⁶

A. Investment in R&D

The investments in R&D by the leading pharmaceutical companies have been soaring through the years. In the year 2002, the top companies invested more than US \$35 billion in R&D. Industry sponsored studies have also increasingly raised the bench mark for developing a new molecule. In 2001, a study conducted by Tufts University concluded that the average cost of pharmaceutical R&D was US \$802 million to develop a new drug and bring it to the market. The 2008 study by Tufts University set the cost to develop a new biopharmaceutical at above US \$1 billion. The study concludes that the total biopharmaceutical R&D costs include the cost of molecules that fail in testing and the time cost of investing in development years before any potential returns can be earned. Time costs account for more than half of the total cost of recombinant proteins and monoclonal antibodies that entered the clinical testing pipeline from 1990 to 2003.⁷

B. Dwindling Pipelines

But the huge expenditure on R&D has not translated into the development of new drugs. This is evident from the 2003 report of the United States Food and Drug Authority, as detailed in Table 1 below.

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5. A.J. Barrett et al., *Feeding the Pipeline*, Bus. Wk. 78-82 (2003).
 6. F. Arner & A. Weintraub, *J&J: Toughing out the drought*, Bus. Wk. 84-85, 64 (Jan, 2004).
 7. *Outlook* (Tufts Centre for the Study of Drug Development, 2008) available at <http://csdd.tufts.edu>.

Table 1: New Drugs Approved by the US FDA between 1996 and 2003

Year	New Drugs Approved (NDA)	New Molecular Entities (NME)
2003	14	9
2002	11	7
2001	10	7
2000	20	9
1999	28	19

These issues faced by pharmaceuticals have led the industry to devise ways of re-inventing inventions. Major pharmaceutical companies are big organisations which need huge profits to sustain the growth rate. With the pipeline of new drugs dwindling over the years and with many products going off patent protection soon, pharmaceutical companies have resorted to new ways of patenting old inventions.

VII. PAINTING THE SWAN BLACK

In the field of innovation, a Black Swan refers to a rare, high impact and unpredictable innovation that can bring unprecedented success to any business. Most of the path-breaking, radical technologies that we see around us are Black Swan Innovations. And every technology company is looking out for Black Swans and the means of protecting them. The law of patents offers the most-comprehensive means of protecting the Black Swan. While it is one thing to offer patent protection for the genuine Black Swans – the real, radical innovations that are novel and non-obvious, it is entirely another thing when old and obvious innovations are patented as new – an ordinary swan painted black! “Painting the swan black” metaphorically refers to passing of a white swan as black (patenting inventions that are obvious) or doing a paint job to refurbish an old black swan to look new (making superficial changes to an earlier invention to qualify for a fresh grant). Both can have adverse affect on business and the development of technology.

If used effectively, pre-grant opposition procedure can act as a touchstone to test the genuineness of an invention. It can be used to separate the real Black Swans from the ones that are painted black. While pre-grant opposition could be criticised, as it is done in the United States, on the ground that it could

frivolously delay the grant of a patent, the benefits that arise out of having a pre-grant opposition procedure in a patent system far outweigh the ills that malign it. Frivolous pre-grant opposition could be disciplined by imposing punitive costs on the pre-grant opponent.⁸ It is an inherent disposition of the patent system that it balances the tension between rewarding some inventors at the cost of inhibiting the activities of others. Pre-grant opposition should be seen as yet another balancing act which counterweighs the need to bring outside information into the patent office against the probable delay in asserting one's exclusivity over the patent when it is granted.⁹

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8. See *Enkay Rubber's Application*, India Patent No. 193339 (1342/Del/1999), where the Controller observed that the opponent had at every point of time requested for an adjournment and had adopted various ways to delay the proceedings and granted compensatory costs of Rs 32,000 for delay in the grant of patent caused by the opponent.
 9. This assertion of exclusivity is nothing but stopping others from using the invention. Pre-grant opposition does not eat into the life of a patent as the life of a patent accrues from the date of making the application. Pre-grant opposition, at best, delays the right of the applicant to stop others from using and exploiting the invention which accrues only after the grant of the patent.