

## Viagra

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Viagra is a celebrated and remarkable pharmaceutical object. Its 1998 entry into the market was accompanied by media attention on a scale barely preceded for any medicine let alone one that doesn't actually save lives. It swiftly became a global social phenomenon, turning an embarrassing and sometimes distressing personal condition rarely talked about into a recognised medical problem susceptible to a pharmaceutical solution, one that people could hardly stop talking about. In doing so Viagra helped extend the boundaries of medicalization: the trend by which any deviation from supposedly normal human well-being is increasingly being reduced to a condition for which medical treatment in some form or another is, or should be, available.

What *is* Viagra? Viagra cannot be *wholly* defined by what it is made of, what it is for, by what it looks like, or by what it does when the human body absorbs it, essential factors as these undoubtedly are. In fact, what Viagra is, and is not, is determined not just by its composition and function but by the regulatory regimes controlling its use, and especially the intellectual property rights used to protect it, the scope of these rights, and their boundaries with the rights, duties and freedoms of others, and with the public domain. Indeed, the best definition we can probably come up with would be this: 'a sildenafil-containing Erectile Dysfunction treatment in the form of a blue diamond-shaped tablet called Viagra'. The purpose of this chapter, then, is to investigate the dynamic relationship between Viagra and intellectual property, and in doing so see how far we can reduce Viagra to a fixed and bounded legal construct 'created' by intellectual property law.

Viagra, like medicines other than mixtures, is a highly specific product in pill form containing a single active ingredient and other substances called excipients whose typical functions are to protect it on its journey through the body, control the active ingredient's rate of absorption, and enhance palatability. Scientifically the active ingredient can be identified as either: (i) the tongue-twisting 1-[[3-(6,7-dihydro-1-methyl7-oxo-3-propyl-1H-pyrazolo[4,3-d]pyrimidin-5-yl)4-ethoxyphenyl]sulphonyl]-4-methylpiperazine, as (ii) the somewhat simpler  $C_{22}H_{30}N_6O_4S$ , or as (iii) sildenafil citrate, or its non-proprietary generic name of sildenafil. For obvious reasons we will settle for the latter name.

To say that Viagra *is* sildenafil citrate is surely a statement of fact. However, Pfizer stakes its ownership claims in far more subtle ways than that. This is why it is more accurate to say that Viagra *has* – rather than *is* – sildenafil citrate. Even then, this does not mean that only Viagra has sildenafil citrate. Pfizer's management of its intellectual property surrounding Viagra does not make things that simple. Indeed, the boundaries secured and guarded by

the patent and trademark rights around 'Viagra' are much broader than the active ingredient alone, albeit not as broad as Pfizer, the company responsible, would have liked.

Sildenafil was discovered with the aim of producing cardiovascular benefits to patients. More specifically it purposely disrupts a naturally occurring enzyme called phosphodiesterase type 5 (PDE5) in order to deal with disorders like hypertension and angina. As such it was intended as a better ('me-too') version of a failed and now largely forgotten drug candidate called zaprinast. The initial results from tests on patients started in 1991 were disappointing in part due to the chemical's short half-life in the body making its effects a little too temporary. However, a group of people given the substance, reportedly Welsh miners, described increased incidences of erections. It turned out that PDE5 inhibition enables the flow of blood into the penis by relaxing certain muscle in the erectile tissue.

Medicines must be *for* something. What was Viagra for? Aphrodisiacs are not medicines. Consequently, Erectile Dysfunction (ED) had to be 'invented' in order for sildenafil to become the prescription medicine Viagra rather than a recreational drug like ecstasy. It is worthy of note here that the ED concept is both mechanical and reductionist. It really gets to the point, that it's the penis that needs fixing. In contrast, women have the rather blander and less specific Female Sexual Disorder (FSD) which implicates no organs or body parts. Pfizer did not invent ED as such, but it invested huge sums in promoting the medicalization of the condition, one previously thought either to be too trivial or inherently psychological to 'deserve' its own drug. This of course suited many men who could point to their 'condition' as a medical problem that they should not be blamed for.

Central to any marketing strategy in the pharmaceutical industry is to have a good name for the product, one which directs those purchasing drugs to that product and not to alternative ones. Without question, Viagra® as a product name has been hugely successful, generating vast sums of money for Pfizer. Registration of the word mark is of course the first step in protecting the name of your drug (or any other product). Being ready to guard the mark through enforcement actions and oppositions to the registration of similar marks is essential. Doing so has ensured that there is no such thing, for example, as 'Natural Viagra', at least in law, notwithstanding attempts still made to use the term for herbal products of varying levels of dubiety. Keeping control over use of 'Viagra' in the market place helped prevent it becoming a genericised synonym of 'aphrodisiac', something that was assisted by Pfizer's own educational programme to enhance public awareness of ED as a condition. Here trademark and patent strategy supported each other, as they often do in this business. Until Pfizer informs us otherwise, Viagra® *must* consist of sildenafil citrate, a substance patented in the early 1990s. As such, this remains a defining quality. On the other hand, when sildenafil citrate is prescribed for pulmonary arterial hypertension (PAH), it is not Viagra® but Revatio®. All Viagra is sildenafil citrate but not all sildenafil citrate in the form of

a pill is Viagra. In this sense one can say that Pfizer is narrowing the boundaries of its monopoly to accommodate another one, so that it is sildenafil *only* when indicated for erectile dysfunction. But in a sense it is even more specific than this. Pfizer has numerous trademarks relating to Viagra include ones covering the blue-colored and diamond-shaped appearance of the tablet, and even a European design right. Thus in the minds of the consumer and indeed the general public Viagra is that 'little blue pill'. In this case the specificity of Viagra's look will prevent generic firms selling sildenafil – its non-proprietary name – from making their copies look like Pfizer's original product.

Pfizer, as one would expect, did its utmost to expand the scope of its monopoly on the product as much, and for as long, as possible. The challenge facing the company as for others is that after its initial discovery as a novel substance with a plausible medicinal use, it turned out to be much more effective for something else, in this case for the main reported side effect. Thankfully for the industry it is possible to file patent applications for new medical indications of substances that themselves lack novelty having been discovered earlier. Pfizer availed itself of this possibility in those areas of the world where such patenting is allowed.

As the first PDE5 (or PDEV to which it is sometimes abbreviated) inhibitor on the market and the first for treating erectile dysfunction, Pfizer was understandably keen to associate its invention with PDE5 inhibition as a unique feature. Otherwise it would have been impossible to block the market entry of follow-on PDE5 inhibitors from Pfizer's competitors. It sought to do this by claiming in its new use patents a class of compounds of which sildenafil citrate was one member sharing the ability to inhibit the action of PDE5. However, doing so helped to render these patents vulnerable to attack. Consequently, Pfizer was unable to prevent the market entry of me-too rivals Cialis® and Levitra®.

The UK and European patents were revoked or successfully opposed primarily on grounds of obviousness. The Chinese State Intellectual Property Organization revoked the counterpart Chinese patent in 2004 on similar grounds. In 2012, the Canadian Supreme Court revoked the patent there for insufficient disclosure. The fate of the United States patent on the use of Viagra for ED, which remains in force until 2019 albeit with reduced scope, is particularly fascinating.

In February 2010, the Board of Patent Appeals and Interferences of the US Patent and Trademark Office decided on an appeal by Pfizer relating to the following claim which the examiner had rejected:

A method of treating erectile dysfunction in a male human, comprising orally administering to a male human in need of such treatment an effective amount of a selective cGMP PDEV inhibitor, or a pharmaceutically acceptable salt thereof, of [*sic*, or] a pharmaceutical composition containing either entity.

By its interpretation of the law, the Board set a reasonably high bar for anticipation (that is, novelty negation) by prior publication:

A reference is anticipatory under § 102(b) when it (i) discloses each and every element of the claimed invention, either explicitly or inherently, and (ii) enables one of ordinary skill in the art to make the invention.

Four of the references held by the examiner to anticipate the claim disclosed use of Yin Yang Huo ('horny goat weed') in traditional medicine. These together were referred to by the Board as the 'Yin Yang Huo references'. For the Board, the key point at issue was whether or not these references 'describe oral administration of the selective PDEV inhibitor icariin *in an amount effective to treat ED* [erectile dysfunction]'.

In his rejection, the examiner had relied on expert testimony showing that Ying Yang Huo contains icariin and that this substance is effective as a selective cGMP PDEV inhibitor. The question then arose of whether or not the Yin Yang Huo oral preparations as used in traditional Chinese medicine as an aphrodisiac that were described in the publications effectively delivered icariin to the patients and therefore anticipated the claim. In fact, of the four relevant publications one of them (by Yin) did not mention icariin; evidently the preparation was not well known to this author by its chemical composition. In arguing its case, Pfizer observed that the Yin article's 'disclosed treatment comprises a mixture of Yin Yang Huo and Tu Si Zi, as well as yellow rice wine, genital massage, rest, bathing in a herbal mixture, and abstinence from intercourse and, therefore, does not establish that the treatment effect was due to Yin Yang Huo alone'. Accordingly, Pfizer's lawyers claimed, this was not enabling. The Board rejected this view, concluding that the disclosure just had to enable the oral delivery of enough of the enzyme inhibitory substance to treat erectile dysfunction, which it did. Therefore, each of the four publications held by the examiner to anticipate claim 24, including Yin's, were accepted also by the Board.

Is Viagra no more nor less than what Pfizer tells us it is, in accordance with the intellectual property rights that it owns? Of course, the market (and marketing) power lent by intellectual property rights over Viagra allows a large measure of control over how the product is represented to the public *as a medical entity*. However, what patents and trademarks could never do is enable Pfizer to control all of the narratives, stories, meanings and representations about Viagra in society including popular culture. Consumers, social commentators, and comedians, among others, have also had much to say about Viagra and Erectile Dysfunction. That is of course a measure of its success. Viagra, whatever it is and whatever it is for, has joined aspirin, Valium, Prozac and of course 'the pill' as a cultural icon, one that for Pfizer has been extraordinarily profitable. Indeed, Viagra may well be the first billion dollar a year drug whose sales were so much attributable to direct-to-consumer publicity and attendant media hype underpinned by a creative mix of patents and trademarks.

### Further reading

Hossein A. Ghofrani, Ian H. Osterloh and Friedrich Grimminger (2006), Sildenafil: from angina to erectile dysfunction to pulmonary hypertension and beyond. *Nature Reviews Drug Discovery* 5: 689-702.

Meika Loe (2004), *The Rise of Viagra: How the Little Blue Pill Changed Sex in America*. New York: New York University Press.

Annie Potts and Leonore Tiefer (editors) (2006), 'Special issue on "Viagra culture"'. *Sexualities* 9(3).