Oral Contraceptives: 
Yasmin®, Yaz® and Ruby®

Background:
A generic version of a popular birth control pill has been blocked from entering the South African market for the past three years, due to a series of court cases concerning a patent on the original product. United States and European courts have both rejected the validity of the patent, which is held by multinational pharmaceutical company Bayer. A South African court, however, has upheld the patent, preventing marketing of a 30% cheaper product.

This case clearly illustrates several problems with South Africa’s current patent laws, which allow companies to maintain their monopolies by filing for multiple patents on medicines, and make it difficult to overturn low-quality patents after they are granted. Consumers and local industry pay the price for these legal problems—in this case, over R11 million per year, because no generic competition exists. The Department of Trade and Industry urgently needs to finalise a national intellectual property policy that will change the way medicine patents are granted and upheld in South Africa, and protect people’s lives instead of Big Pharma’s profits.

Facts about drospirenone (DSP)/ethinyl estradiol (EE)

Originator Manufacturer:
• Bayer AG (markets as Yasmin® and Yaz®)

Generic Manufacturers:
• South Africa: Pharma Dynamics (markets as Ruby®—litigation brought by Bayer over patent has blocked active marketing)
• Globally: Teva, Actavis, Sandoz, Lupin, Barr

Recommended Dosage: One pill taken every day, no more than 24 hours apart.¹

Registered indications:
Yasmin, Ruby and Yaz are oral contraceptive for use by women to prevent pregnancy. Yaz is also registered as a treatment for premenstrual dysphoric disorder (PMDD) and for moderate acne in women who are using the pill for birth control.² ³

Is there a difference between Yasmin, Yaz, and Ruby?
Yasmin and Yaz are both manufactured by the pharmaceutical company, Bayer. They contain the same active ingredients, which are used to prevent pregnancy, but Yaz features a lower dose of synthetic estrogen. In other words, Yaz is a modified version of Yasmin, released at a later date—not a new drug.

Ruby is manufactured by Pharma Dynamics. Ruby is a generic version of Yasmin, meaning it is identical to Yasmin both chemically (in terms of the amount of the active pharmaceutical ingredient), and in terms of clinical efficacy and benefit. As with most generic products, it is cheaper than the originator product.

³ "Failing to provide affordable contraceptives is equivalent to oppression of women. Big Pharma monopolizes the health market because they have money for legal battles…it’s the pharma mafia! Fix the Patent Laws!!!" ~ Dr. Lerato Masemola, Johannesburg, Gauteng

This briefing document was compiled by Doctors Without Borders South Africa for the Fix the Patent Laws campaign.
Is Yaz a “better” version of Yasmin?
Yaz has more registered indications than Yasmin, which might suggest that Yaz is a better product. This is not necessarily true. Drug companies decide which indications to register their product for, provided they have supporting data. Companies can also selectively choose not to register a product for certain indications, even if clinical evidence supports such usage. For instance, a number of oral contraceptives—including Yasmin—are prescribed “off-label” by physicians to treat the same indications for which Yaz is registered.4

One of the reasons for adding additional indications for newer products may revolve around a company’s marketing strategy for a drug. For example, if companies can get patents easily for small modifications to products (as they can in South Africa), it may benefit a company’s profitability to portray products that are still under patent as “improved” compared to off-patent products. This is typically an attempt to switch patients onto more expensive medicines, and less frequently about significant clinical improvements—several studies have found that up to 75% of medicines approved in countries like the U.S. and Europe offer “no therapeutic benefits over existing medicines.”5

How big is the market for these drugs, and how much to women pay?
Yaz and Yasmin are the first and second top-selling contraceptive drugs by revenue in South Africa, respectively. Approximately 141,000 women used Yaz or Yasmin products in South Africa in 2013. Neither product is purchased by the Department of Health; instead all sales of Yaz and Yasmin are through the private sector—either through independent purchase by individuals, or through medical savings accounts. Yaz/Yasmin is also Bayer’s fourth best-selling drug globally, with over €853 million (R12.1 billion) in annual sales6. Emerging markets, including South Africa, comprise 37.5% to Bayer’s total annual sales of these products.7

Pharma Dynamics is not allowed to market Ruby in South Africa—their generic version of Yasmin is not yet authorized for sale. This is because Pharma Dynamics questioned whether the patent was actually examined prior to being granted, Pharma Dynamics registered a generic version of Yasmin in South Africa in 2011—marketed as Ruby—it was to be available through the private sector at a price of R80.93 per pack, a 30% cost reduction from Yasmin (see table below for prices).

If everyone on Yasmin had made the switch to Ruby, South African women would have saved over R11 million per year in total.

South African sales of contraceptives containing DSP+EE

<table>
<thead>
<tr>
<th>Manufacturer</th>
<th>Brand Name</th>
<th>Units Sold in SA (Oct. 2012 -Sept. 2013)*</th>
<th>Annual revenue in ZAR (Oct. 2012-Sept. 2013)*</th>
<th>Price per pack of pills in private sector*</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bayer</td>
<td>Yaz</td>
<td>793 559</td>
<td>89 404 172</td>
<td>R139.80</td>
</tr>
<tr>
<td>Bayer</td>
<td>Yasmin</td>
<td>903 531</td>
<td>84 196 100</td>
<td>R115.62</td>
</tr>
<tr>
<td>Pharma-dynamics</td>
<td>Ruby</td>
<td>0</td>
<td>0</td>
<td>R80.93</td>
</tr>
</tbody>
</table>

Why can’t the cheaper product be made available in South Africa?
The Pharma Dynamics product cannot be sold because of a patent infringement case. Bayer’s primary patent on the compounds that make up Yasmin and Yaz expired in South Africa in 2010. Anticipating this patent’s expiration, generic company Pharma Dynamics registered a generic version of DSP+EE. However, Bayer has secondary patents on Yasmin which only expire in 2022 and 2024. These patents cover the size of the synthetic hormone ingredient in Yasmin, as well as the rate at which the drug’s active ingredient dissolves.8

When Pharma Dynamics launched its product, Bayer obtained a court order against Pharma Dynamics regarding a secondary patent, forcing the generic off the market in South Africa. Pharma Dynamics was found to be infringing upon Bayer’s 2004 secondary patent, but the generic company subsequently filed a counterclaim in 2013, requesting that the Bayer patent be revoked. Because patent applications are not examined prior to being granted, Pharma Dynamics questioned whether the patent was actually

---

8 SA CIPC. Patent numbers ZA200201668 and ZA200404083.
valid when compared to the national patentability criteria. If the patent was not valid in the first place, then Pharma Dynamics’ could not be infringing upon it. This counterclaim was dismissed, but Pharma Dynamics appealed.

A September 19, 2014, decision by the Supreme Court of Appeal in Bloemfontein determined that Pharma Dynamics’ Ruby infringed upon one of Bayer’s patents on Yasmin, and that Bayer’s patent in question was valid.9 This secondary patent regarded how the product was absorbed in the body—except that Yasmin has always been made in this way, since coming on the market in the early 1990s, and the patent was not filed until 2004. The judge determined that the patent was inventive because what was discovered about how the drug worked in the body was counterintuitive to tests conducted in the laboratory.10

The same secondary patent being upheld in South Africa has been revoked by courts in both Europe and the USA, where generic versions of DSP+EE have already available for several years. These rulings found the patent invalid due to its obvious nature—the change made by Bayer to DSP+EE did not vary from previous industry know-how. This means that while generics are available in the markets where most of the initial investment in drug research and development was made (namely, the U.S. and Europe), countries like South Africa will continue to pay high prices for another decade.

How do South Africa’s patent laws block access to cheaper generics?

Patents on medicines block generic competitors from entering the market, and allow patent holders to charge high prices as long as they maintain a sales monopoly.11 Companies often try to engage in patent “evergreening”, which is what Bayer has done in the case of Yasmin. This means that after applying for an initial patent on a new compound used to produce a drug, a company will also apply in subsequent years for additional patents that cover small changes to these compound or products. These “secondary” patents may cover new formulations, combinations with other drugs, or new uses of the drug. Secondary patents can block generic competition for years, or even decades after the initial 20-year patent expires. Since 2002, Bayer has filed for 11 different patents in South Africa on just one of the active ingredients in Yasmin—a very clear illustration of how the current system allows over-patenting, and frustrates generic entry.12

Patent evergreening is a common problem in South Africa because the criteria for granting a patent is not very strict (meaning the bar for innovation is set very low), and is not enforced. One study found that up to 80% of South African pharmaceutical patents did not meet national criteria.13 The key reason for this is that patent applications are not examined to ensure compliance with national criteria in the Patents Act. This allows Big Pharma to maintain sales monopolies, and keep medicine costs artificially high.

However, in some cases in South Africa, a generic company may decide to launch a product in spite of existing secondary patents. This may occur when a generic company thinks that secondary patents are low-quality and do not stand up to the country’s patentability criteria. When this happens, an originator company may know that the patent is low-quality, and decide not to enforce it. In this case, the generic comes on the market. However, if the originator company does decide to enforce their patent—like Bayer did—the matter will go to the courts.

The court process also tends to favour the originator company, which is a further deterrent to generic companies that want to challenge patents. The law tends to rule in favour of the party that will suffer the greatest damage from a decision against it—this ‘balance of convenience’ is often interpreted in financial terms for the companies, and does not consider public health or consumer benefits that might arise from deciding in favour of a generic company.

There are effective birth control pills that are much cheaper in South Africa than any of these products—so why is this case over patents important?

9 Pharma Dynamics (Pty) Ltd v Bayer Pharma AG (468/13) [2014] ZASCA 123 (19 September 2014).
10 Child K. Yasmin takes out Ruby. 03 October 2014 http://www.timeslive.co.za/thetimes/2014/10/03/yasmin-
takes-out-ruby
system/

This briefing document was compiled by Doctors Without Borders South Africa for the Fix the Patent Laws campaign.
This court case is not only about birth control pills—it is about people in South Africa being able to access the lifesaving medicines they need, or having affordable options of medicines that they choose to take. If a legal battle over patents on birth control pills can prevent availability of lower-cost generic products, there is nothing to prevent the same scenario from happening with lifesaving medications for cancer, drug-resistant tuberculosis, hepatitis, or any number of medicines. South Africa knows this all too well, from the many years and legal battles that were required to stop Big Pharma from enforcing patents on affordable antiretroviral medicines. Many thousands of people living with HIV/AIDS could not access treatment due to the high cost. These battles can continue to be fought drug-by-drug, disease-by-disease, but changes to the system for granting patents could prevent some of these battles from having to be fought in the first place.

How could the patent laws change to promote generic competition?
Developing and industrialised countries who are members of the World Trade Organisation are required to grant patents on new pharmaceutical compounds. However, countries also have the right to set very high standards for what deserves a patent. Many countries do not consider secondary patents on medicines to be innovative enough to deserve a patent. This is particularly true when the patent applied for covers a change that is common knowledge within the pharmaceutical industry.

Countries such as India and Argentina have set very strict patentability criteria, in order to limit evergreening. This protects public health and allows for greater consumer choice by promoting earlier access to more affordable generic medicines. South Africa can follow suit.

The Department of Trade and Industry (DTI) is in the process of finalising a National Intellectual Property Policy, which will lay the foundation for changes to South Africa’s patent laws. The DTI released a draft policy for public comment in September of 2013. This outlined a number of important reforms that would be important for improving access to more affordable medicines. All of these reforms have been implemented in other developing and industrialised countries, and all of them are legal under international trade agreements. These reforms include:

- Strengthening the national patentability criteria to would limit evergreening.
- Establishing a patent examination system, to enforce national patentability criteria and reduce patent evergreening.
- Allowing for patent opposition before and after a patent is granted, by a broad range of third parties. This allows third parties to provide evidence to the Patent Office to show that an application does not meet patentability criteria, or that granting a patent would have a detrimental impact on public health. This should be an administrative, rather than court-based procedure, and assist the Patent Office in reducing the number of low-quality patents that are granted.

The Pharmagate scandal—why is Big Pharma so opposed to patent law reform?
In January 2014, a scandal broke in the South African media, and was subsequently dubbed “Pharmagate”. Twenty-five multinational pharmaceutical companies—including Bayer—had developed a covert strategy to finance South African “front” organisations, and have these organisations publicly oppose intellectual property reform that would protect people’s right to health in South Africa. If countries have high standards for earning patents, it means companies would have to invest in developing new and innovative medicines, rather than just tweak old drugs. Big Pharma doesn’t want reform, because they care more about profits than people’s lives.

What can I do to change things?
Your government and multinational companies should know that you are tired of paying too much for patented medicines in South Africa. The Pharmagate scandal shouldn’t be tolerated, and the Department of Trade and Industry needs to finalise a National Intellectual Property Policy that promotes the right to health, so that the patent laws can start to change!

If you want access to cheaper generic birth control, tell @Bayer to back off in South Africa, and stop enforcing their patent on Yasmin! Tweet @the_dti @HealthZA and at your Parliamentary representative and demand they @FixPatentLaw

---

14 [http://patentoppositions.org/how_to_build_an_opposition#opposition]

This briefing document was compiled by Doctors Without Borders South Africa for the Fix the Patent Laws campaign.