The Gynefix® Patent

A Belgian invention

Elke Hoedt

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Promoter:

Prof. Dr. Geertrui Van Overwalle

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Preface

One day in the 90's I read a small article in a Belgian newspaper about a 'Belgian invention, great in United States'. It described the contraceptive intra-uterine Gynefix® device without hormones, invented by the Belgian Prof. Dr. Dirk Wildemeersch.
Some of my friends used the pill as a contraceptive or as a treatment against acne. Some have been prescribed a pill with a concentration of hormones too high compared to what their body could handle so it for example increased their fat mass among other undesired side effects. Others found it difficult to comply with the fact they should take that pill every day at the same time or they then would risk getting pregnant.
I decided that this daily routine would be a risk for me and that hormones in general couldn't be much good for the body. I preferred a contraceptive without hormones and kept the article about Gynefix® until the time was appropriate.

Several years later, when choosing the topic of this thesis, I wanted to write about something I believed in, something I wanted to know more about: Gynefix®. In this way I had the chance not only to study the science part of Gynefix® but also to absorb myself in the juridical background of this invention.

For making it possible for me to realize this thesis, I would like to thank Prof. Dr. Geertrui Van Overwalle for the professional guidance and advice, Prof. Dr. Dirk Wildemeersch for the cooperation and the useful information and Alain Colens of the Patent Office Hansens for giving me full access to the Gynefix® file.

And last but not least special thanks goes out to some people close to me:
My parents Marniek and Marie-Jeanne for supporting me morally and financially to finish this Master; my brother Kim and my flatmate Alfonso Blanco Suarez for listening

with patience to my monologues whenever I was getting too enthusiastic about this Gynefix®.

Samenvatting Nederlands

Het doel van deze scriptie is de problematiek in de toekenning van het Patent voor Gynefix® in de Verenigde Staten te bespreken samen met de gekende rechtspraak rond patentaanvragen voor gelijkaardige contraceptieve middelen voor vrouwen.

In **Deel 1** wordt de wetenschappelijke evolutie van intra-uteriene contraceptieve middelen besproken. Een introductie van ongewenste zwangerschappen tot preventie van zwangerschap is terug te vinden in Hoofdstuk 1. Verschillende IUDs die geen hormonen afscheiden (Hoofdstuk 2) worden qua efficiëntie en betrouwbaarheid samen met hun voor- en nadelen vergeleken met IUDs die wel hormonen afscheiden (Hoofdstuk 3). In Hoofdstuk 4 worden de vooroordelen in verband met IUDs aangepakt om tot een conclusie te komen in Hoofdstuk 5.

In **Deel 2** wordt een korte introductie gegeven omtrent patentenrecht voor het hele proces van het toekennen van het Patent aan Gynefix® in de Verenigde Staten uit de doeken wordt gedaan. Van 3 verwerpingen van de patentaanvraag tot de uiteindelijke toekenning van het patent.

Deel 3 behandelt de bestaande rechtspraak van de Board of Appeal van het Europees Patenten Bureau omtrent het type contraceptieve uitvindingen als Gynefix®.

Deel 4 concludeert deze thesis over het Gynefix® patent.

Als toemaatje wordt in **Deel 5** het commerciële succes van de Gynefix® IUD toegelicht.

Résumé Français

Le but de ce thésis est de débattre la problématique autour du brevet pour Gynefix® aux États-Unis avec la jurisprudence connue autour des applications pour les moyens contraceptifs similaires.

Dans la **Partie 1**, l'évolution scientifique des moyens contraceptifs intra-utérins est discutée. Une introduction dès grossesses indésirées jusqu'à la prévention d'une grossesse est à retrouver dans le Chapitre 1. Différents IUDs sans hormones (Chapitre 2) sont comparés avec des IUDs avec hormones (Chapitre 3) en ce qui concerne l'efficacité et la fiabilité et leurs avantages et inconvénients. Dans le chapitre 4 les préjugés concernant IUDs sont résolus pour venir jusqu'à une conclusion dans le chapitre 5.

Dans la **Partie 2**, une courte introduction est donnée concernant le droit des brevets avant d'expliquer le processus entier de l'attribution du brevet pour Gynefix® aux États-Unis. Des 3 rejets de la demande de ce brevet jusqu'à accorder le brevet final.

La **Partie 3** traite la jurisprudence existente des Chambres de Recours de l'Office Européen des Brevets concernant des inventions contraceptives comme Gynefix®.

La **Partie 4** conclut ce thesis au sujet du brevet Gynef®.

Et la **Partie 5** est un extra concernant le succès commercial du IUD Gynefix®.

Summary English

The goal of this thesis is to discuss the problems in granting the Patent for Gynefix® in the United States together with the known jurisdiction on patent applications for this type of contraceptive IUDs for women.

Part 1 deals with the scientifical evolution of contraceptive IUDs. Chapter 1 gives an introduction from undesired pregnancies to prevention of pregnancies. Several non-hormone-releasing IUDs (Chapter 2) are being compared with hormone-releasing IUDs (Chapter 3) at the level of efficiency and reliability together with their (dis)advantages.
In Chapter 4 the judgements against IUDs are being tackled to come to a conclusion in Chapter 5.

Part 2 reviews shortly the patent system before examining the process of granting a Patent to Gynefix® in the United States. From 3 rejections to the final acceptation and granting of the Patent.

Part 3 considers the known jurisdiction of the Board of Appeal of the European Patent Office concerning this type of contraceptive inventions.

Part 4 concludes this thesis.

As an extra **Part 5** slightly touches the commercial succes of the Gynefix® IUD.

Glossary

In order of appearance:

1. **Haemostatic effect**: effect that stops the bleeding.

2. **Myocardial infarction**: a term used to describe an irreversible injury to the myocard (heart muscle).

3. **Oestrogen**: a generic term for the female sex hormones. In humans, oestrogen is mainly formed in the ovaries. It is responsible for the development of the femail secondary sex characteristics and during the menstrual cycle it acts on the female genitalia to produce an environment suitable for the fertilization, implantation and nutrition of the early embryo.

4. **Venous thromboembolism**: obstruction of a venous blood vessel with substances carried by the blood stream.

5. **Amenorrhea**: the absence or discontinuation of the menstrual blood loss.

6. **Levonorgestrel**: a progestational hormone with actions similar to those of progesterone, used for contraception, control of menstrual disorders.

7. **Progesterone**: produced in the corpus luteum as an antagonist of oestrogen, promotes the proliferation of the uterine mucosa (mucus layer) and the implantation of the blastocyst, prevents further follicular development.

8. **Prostaglandins**: a protein purified originally from the prostate regulates cellular activities, especially inflammatory reponses where they act as vasodilators in the vascular system.

9. **Fallopian tubes**: the paired tubes which connect the ovaries to the uterus and conduct the egg to the uterus.

10. **Cervix**: the lower and narrow end of the uterus.

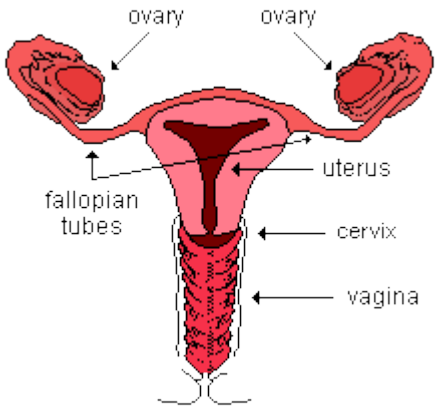

Figure A. The female reproductive system (out: www.anthro.palomar.edu/biobasis/bio2.htm)

11. **Endometrial**< endometrium: the tissue lining the uterus, it is sloughed off during the menstrual period and grows back afterwards untill the next period.

12. **US FDA**: United States Food and Drug Administration.

13. **Nulliparous women**: women who never gave birth before.

14. **Myometrium**: muscled layer of the uterus.

15. **Atrophy**: a diminution in the size of a cell, tissue, organ or part.

16. **Ectopic**: an organ or other structure which is positioned abnormally within the body.

PART I.

Scientific background of the Gynefix® Patent

Chapter 1. Introduction

1. Alarming increase in adolescent pregnancies.

Recent population studies have established the alarming **increase** of teenage pregnancies worldwide. [1, 2, 3, 4] We are facing the largest-ever generation of young people entering adulthood as a young parent. Millions of women begin their childbearing in their teens.

The problem is huge since the majority of these pregnancies are **unplanned and unintended**. Some figures speak for themselves: more than 50% of pregnancies in the USA are unplanned, half of them (1.4 million per year) end in termination of which over 50% are women younger than 25 and 22% adolescents. In Western Europe the figures are similar: in the UK, in France and Italy there are roughly 200 000 abortions yearly of which 25% of women who are between the age of 16 and 19.

Teenage pregnancy is unquestionably a **worldwide problem**: 58 per cent of all mothers in sub-Saharan Africa are teenagers. A similar situation is seen in the Philippines, Thailand, India, Pakistan, Bangladesh and Central America. [4] In China, the number of unintended pregnancies and abortions in teenagers has sharply increased during recent years. [5, 6] A large number of these abortions are clandestine and therefore unsafe.

2. Consequences

One of the great challenges of our time is to **reduce** the soaring number of these unplanned pregnancies in adolescent women. If the pregnancy is allowed to go to term (which does not happen in 50% of the cases) [(7)], there are several possible medical consequences such as low-birth, prematurity, intrauterine growth retardation and neo-natal mortality. [(8)] Adolescent pregnancy carries many other risks that have been the focus of intense research activity in recent years. Teenagers who become parents are at greater risk of social and economic disadvantage throughout their lives than those who delay childbearing until their twenties [(9)]

3. Oral contraceptives

The majority of unintended pregnancies are usually the consequence of a **lack of access** to information and services, unwanted sexual relations, unprotected sex or ineffective use of contraception. The latter can result from providing too few options, inadequate information or unsuitable methods for certain subgroups of teenage women. [(10)]

In spite of the wide scale availability of the **pill** (at least in the Western world) the failure rate of the pill is still unacceptably high at 5 per cent due to inconsistent use and discontinuation. To be effective, the pill should be taken every day at the same time, except during menstruation. In case this daily routine is discontinued for 1 or several days, there is a greater risk of pregnancy even when the pill had been taken correctly for the rest of the days. Between 40 and 60 per cent of new pill users discontinue the pill during the first year. The average duration of use of the pill in the USA is only 4.8 months. [(11)]

The same phenomenon has been observed in Western Europe where 50 per cent of adolescents stop using the pill after 3 months. It seems extremely hard for very young women to use the method correctly and consistently. It follows that the contraceptive method failure rates, for methods that depend on user compliance, may be calculated incorrectly and be reported lower than reality. (11)

The **ineffectiveness of oral contraceptive** pills and barrier methods of contraception (e.g. condoms) was shown in studies conducted in young women in the UK who underwent a pregnancy termination. Most women used the condom method, which was followed by oral contraception. Both of these methods were found ineffective because of their user-dependent failures. The aim to prevent repeatedly unwanted pregnancy failed. (12)

With oral contraceptives (OCs) there are also **health related concerns**. As OCs are used by many women (40 per cent of women of the reproductive age and up to 70 per cent in the younger age groups in developed countries), it is important to give attention to their possible harmful effects.

What most users of the "pill" don't know is that it contains hormones that set your hormone household to 'pregnant', meaning: hormone levels are the same as when you would be pregnant. This causes systemic side effects. Fifty years after the advent of the pill, there is still a huge concern about its effect on haemostasis and the occurrence of breast cancer. Observational studies, published in 1996, found a slight increased risk of breast cancer in oral contraceptive users, especially in those less than 35 years of age. (13) There is increasing clinical evidence that the risk of myocardial infarction is increased in women using oral contraception, especially when combined with smoking. (14)

Also epidemiological studies warn about the health risks associated with the oestrogen contained in the OCs, such as venous thromboembolism. There is a slightly increased risk of deep venous thrombosis in women using third-generation oral contraceptive users in comparison to second-generation oral contraception users. [15, 16, 17]

For years the "pill" has been synonymous with contraception. This has regrettably helped to maintain the ignorance of any alternatives beyond condoms and sterilisation, although acceptable alternatives have demonstrated their superior effectiveness.

4. Alternatives

It appears that the **most effective method** for young women is a method that minimises the risk of imperfect use. Like an implanted and long-acting device.

a. Implantable, long-acting steroidal systems.

Over the years many implantable, long-acting, steroidal delivery systems have been developed for contraception. A major advantage of long-acting hormonal methods is that they eliminate the need for specific action at the time of coitus such as putting on a condom, or for daily action, such as the pill. They offer discretion and privacy.
Unfortunately some of them also have disadvantages because they disrupt the menstrual cycle causing breakthrough bleeding, amenorrhea or occasionally heavier bleeding. They can also cause systemic hormonal side effects and there is a higher incidence of weight gain. Furthermore they can also cause a delay in return of fertility. [18]

b. Intra-uterine devices and intra-uterine systems

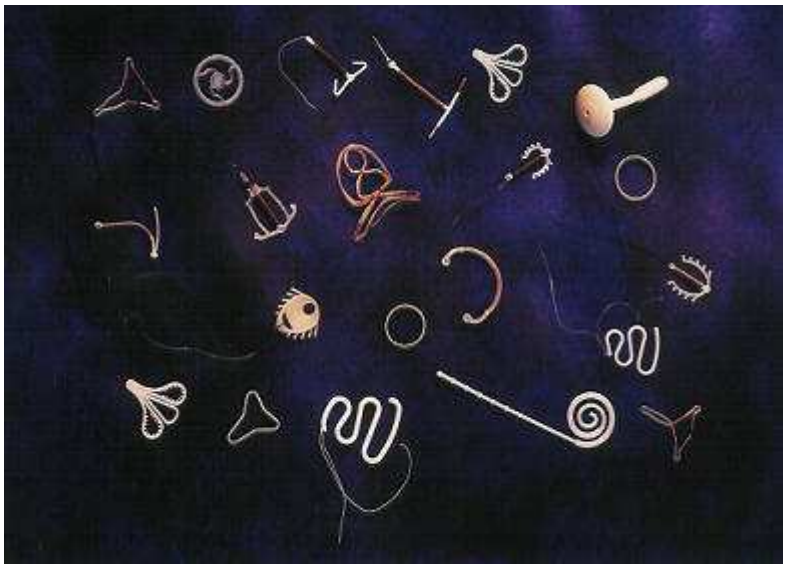

Figure 1. History of intrauterine contraception. [19]

Intra-uterine devices (IUDs, see figure 1) and intra-uterine systems (IUSs) are particularly attractive as they act locally, avoiding systemic effects.

New developments in intra-uterine technology are providing smaller frameless devices (non-hormone-releasing) and devices that combine the features of a frameless copper device with a levonorgestrel system or systems that release levonorgestrel only (=hormone releasing). They may be ideal for use in younger women because they are small, effective and well tolerated. Unlike the pill they are genuinely 'fit-and-forget'. In use, they are much more effective than pills in this age group. Moreover, they are long acting and reversible. The small copper IUDs are also very effective for emergency contraception. [20]

However copper intra-uterine devices do not offer protection against sexually transmitted infections (STIs). Nevertheless they should be offered more frequently as first or second line methods, in combination with condoms.

c. How does the copper IUD work?

Any IUD produces an inflammatory reaction in the uterus that causes the production of white blood cells and prostaglandins.
Copper ions released from the copper IUD enhance the inflammatory response and reach concentrations in the luminal fluids of the genital tract that are toxic for spermatozoa and embryos.

In women using the IUD, the entire genital tract seems affected, because of luminal transmission of the fluids that accumulate in the uterine lumen. The copper IUDs exert their contraceptive effects primarily before fertilization, by killing sperm, by impeding the progress of surviving sperm so they fail to reach the fallopian tubes, by diminishing any survivors' ability to fertilize eggs, or by lowering the chances of survival of any embryo that may be formed, before it reaches the uterus.

Studies on the recovery of eggs from women using IUDs and from women not using contraception show that embryos are formed in the tubes of IUD users at a much lower rate compared to nonusers. Therefore the common belief that the major mechanism of action of IUDs in women is through destruction of embryos in the uterus (i.e. abortion), is not supported by any evidence.

In copper IUD users it is likely that few spermatozoa reach the distal segment of the fallopian tube, those that encounter an egg may be in poor condition. Thus, the few eggs that are fertilized have little chance for development and their possibility for survival in the altered tubal milieu become worse as they approach the uterine cavity. [21, 22]

Chapter 2. Non-hormone-releasing IUDs

1. The Lippes Loop

Figure 2. The Lippes loop. [18]

Dr Jack Lippes developed the plastic Lippes Loop in the early 1960s (see figure 2). He designed the double 'S' shape to accommodate the IUD to the triangular shape of the uterine cavity. At the same time, this design would make spontaneous expulsions less likely.

The plastic material can be easily deformed and stretched, the intrinsic 'memory' enabling the plastic to regain its original shape. When stretched, the double 'S' can be placed in an inserter tube thereby eliminating the dilatation of the cervix. Because of its simple insertion and removal, at that time acceptable rates of pregnancy and side effects were obtained. The Lippes Loop became the standard with which all IUDs were compared. [23]

2. The TCu380A (Paragard)

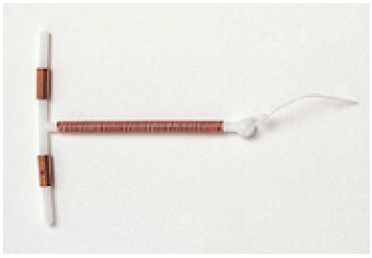

Figure 3. The TCu380A. [18]

Another major development, the TCu380A or Paragard (see figure 3), became available after a long 'incubation' period of research on IUDs about 15 years. [24] Its design was based on anatomical studies conducted on human uteri, which revealed the T-shape of the contracted uterine cavity. Dr. Howard Tatum selected the T-shape plastic model because it seemed logical that the design could cause a minimum of distortion of the endometrial cavity during its maximum degree of contraction (see figure 4).

Having discovered that numerous metabolic inhibitors had a local antifertility effect, Dr. Zipper investigated unilateral insertion of various kinds of metal wire and demonstrated the depressive effect on implantation rates in the uterus of rabbits treated with coppers. Cu-bearing IUDs with a wide variety of shapes and made of many different materials have been introduced and a few of these have been widely tested. [25]

Prototypes of the T-shaped plastic model were developed with increasing copper loads. [26] A high copper content, particularly when added to the cross arms of the T, is efficient in reducing the number of accidental pregnancies which occurred when the IUD moved downwards into the isthmic region of the uterine cavity. But there is an upper limit to the exposed area of copper above which the copper load may promote expulsion of the IUD. [27]

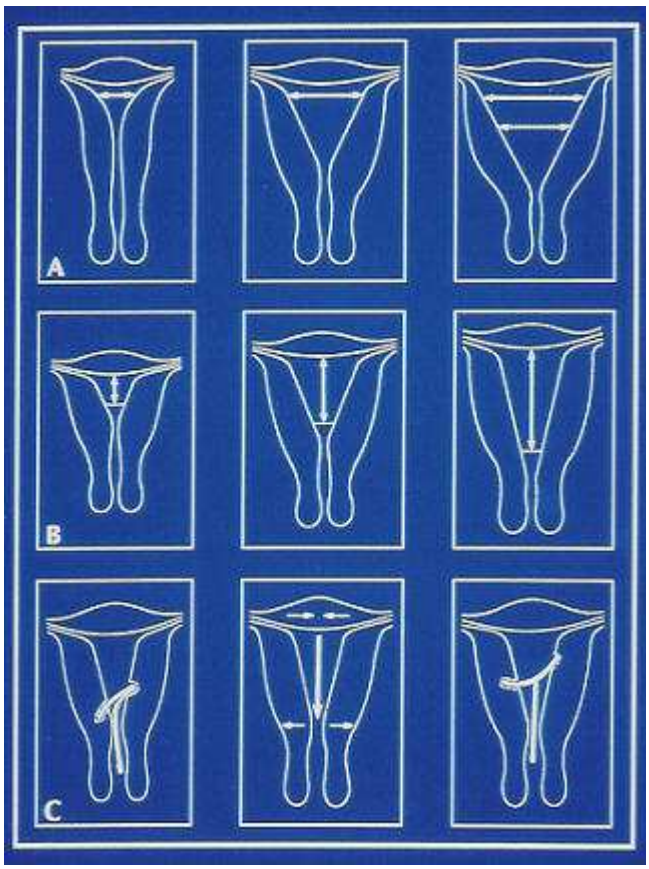

Figure 4. Different shapes of the uterine cavity in 3 different women, compared to different stages in de menstrual cycle. [18]

The copper TCu380A was approved by the US FDA in 1984 and quickly replaced the Lippes Loop as the standard IUD. The TCu380A IUD remained the gold standard against which the effectiveness and safety of all IUDs were assessed. [28]

Following the development of the TCu380A IUD, many new IUDs and IUSs for drug delivery were in development. However, there are only two developments that can truly claim superiority over the copper TCu380A: the frameless copper IUD and the levonorgestrel-releasing IUSs (see chapter 3. Hormone-releasing IUDs).

3. The frameless copper IUD (GyneFix®)

a. GyneFix® standard (330mm²)

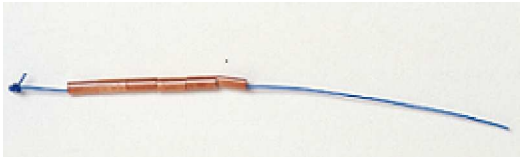

Figure 5. Gynefix® standard (330mm²). [18]

The most common side effects of the framed IUDs are bleeding and pain. The prevalence of the complaint of bleeding and pain vary according to both patient and the type of IUD used. In general: the greater the surface area and size of the IUD, the higher the incidence of removal for bleeding and pain. Young nulliparous women and those with low parity are particularly prone to report bleeding and pain. Disproportion between the IUD and the uterine cavity results from an IUD with a fixed shape and size that is inserted in a cavity that varies in shape and size in each woman. Even in the same woman the uterine cavity changes slightly during the various phases of the menstrual cycle.

The frameless and anchored IUD was developed in 1985 (see figure 5). [28, 29] Six copper tubes are fixed on a length of suture thread. The proximal end is provided with a knot, which is implanted in the myometrium of the uterine cavity with an inserter to permanently secure the IUD in the cavity. With this new concept the dimensional problems are avoided.

GyneFix® has a very low failure rate, which is attributed to the optimal target delivery of the copper ions in the upper part of the uterine cavity. Its performance is further optimised by the atraumatic frameless design, which minimizes the side effects and discomfort experienced with conventional IUDs.

This IUD was considered as the new 'golden standard', compared to the “old” TCu380A.[29]

b. **GyneFix® mini (200mm²)**

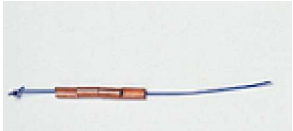

Figure 6. Gynefix® mini (200mm²). [18]

A high copper load is of minor importance with the frameless IUD since the device is attached to the fundus of the uterine cavity. Figure 6 shows a mini version of the GyneFix® IUD (200 mm² total copper surface area) which is only 2cm long (4 copper tubes instead of 6 with the GyneFix® standard).

Clinical trials with the 200-device suggest a high efficacy similar to the higher load (330 mm²) standard version (see figure 5). [30] Its small surface area, however, is 1/3 smaller than the regular GyneFix® IUD, three times smaller than the TCu380A and six times smaller than the Lippes Loop.

The magnitude of the increase in menstrual bleeding is related to the size of the device. With larger types of non-medicated IUD, i.e. Lippes Loop, the blood loss is about 70-80ml, approximately double that of the normal menstrual flow (> 80ml is defined as menorrhagia). The amount of excess bleeding is less (50-60ml) with the smaller framed copper devices (as TCu380A). The majority of users of the GyneFix® mini IUD have normal, no or limited change in menstrual blood loss, this due to the small surface area. [29]

Chapter 3. Hormone-releasing IUDs

Non-hormone- releasing IUDs like Gynefix® on itself don't have any reducing effect on the menstrual bleeding. This can be achieved though by adding the following hormones to the IUD: progesterone or levonorgestrel.

As mentioned above, hormones used as oral contraceptives can cause severe systemic side effects. On the contrary, the IUS's discussed in this chapter release their hormones locally in the uterus so the disadvantages of possible systemic effects are not present anymore. It has a local effect only and very little of these hormones get into the bloodstream.

1. Progestasert IUD

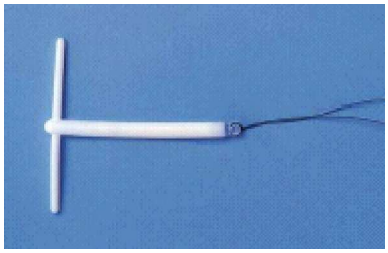

Figure 7. The Progestasert intrauterine device releasing 65 µg of progesterone/day for 1 year of use. (31)

The first to have demonstrated the uterine effects of progesterone, in the late sixties, was Dr. Antonio Scommegna. The initial objective of the development was to reduce the expulsion rate of IUDs by administering uterine relaxing hormones in the uterine cavity.

However, it was found that the intrauterine progesterone release significantly reduced the menstrual blood loss. Dr. Scommegna postulated that the endometrial atrophy elicited by the natural steroid was the reason for the reduced menstrual bleeding and would also be useful to prevent implantation. He conceived a plastic T-shaped IUD, the vertical arm of which was replaced by a reservoir filled with crystalline progesterone (see figure 7).

The Progestasert System never gained wide popularity because of the short (one year) approved effective lifespan of the device. Moreover, the Progestasert probably gives inadequate protection against ectopic pregnancy, which is a serious drawback. [32]

2. Nova-T-LNG-IUS (Mirena)

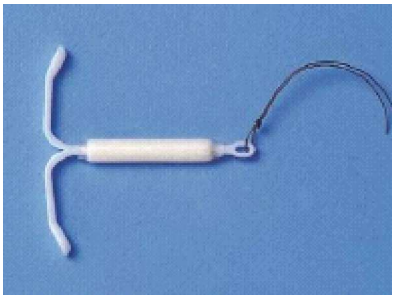

Figure 8. The Nova-T-LNG (Mirena®) intrauterine system releasing 20 µg of levonorgestrel/day for 5 years of use. [31]

Dr. Tapani Luukkainen, the inventor of the Nova-T IUD (a copper-T device with flexible arms) initiated his search for a long-acting steroid-medicated IUD in the early seventies. The Nova-T-LNG emerged in 1976, a Nova-T IUD from which the copper filament has been removed and the vertical arm had been replaced by a small reservoir releasing a constant daily dose of 20µg levonorgestrel (LNG) for at least five years (see figure 8).

The clinical effectiveness of the Nova-T-LNG IUS, resulting from athrophy of the endometrium and the physicochemical changes of the cervical mucus produced by the progestogen, is comparable with that of the combined OC when this is used correctly. Due to the low dose of LNG released, ovulation is often not affected.

The main drawback of the Mirena device is that it produces amenorrhea, which may be a problem for some women particularly in southern Europe and in developing countries.[34] Another drawback of the system is its size, which is too big for use in the small uterine cavities of many nulliparous women. [35]

Hormonal side effects are also a problem in some of the Mirena users. These side effects occur in a significant number of women and decrease with duration of use and age of the woman. [36, 37, 38]

Furthermore, Mirena may be associated with a higher expulsion rate when compared with a copper bearing IUD. [39]

Removal rates for …	**T-LNG-IUD-20 compared to T-Cu-IUD**
Bleeding	Less
Pain	Less
Pelvic inflammatory disease	Less
Oligomenorrhea	More
Amenorrhea	More
Hormonal side effects (as acne, weight gain, nausea, headache, breast tension,…)	More
Irregular bleeding	More
Ovarian cysts	More

Quality of …	**T-LNG-IUD-20 compared to T-Cu-IUD**
Effectiveness	Same
Safety	Same
Longevity	Same
Return to fertility	Same
Insertion	worse due to wider diameter

Table 1. Hormone-releasing T-IUDs compared to non-hormone-releasing T-IUDs. [33]

When comparing the hormone-releasing T-IUDs with the non-hormone-releasing, T-copper IUDs it seems they are both as effective and as safe (see table 1).

A copper IUD seems more ideal for women who don't have an excessive blood loss and who prefer not to use hormones because of the side effects. Compared to a T-IUD which is difficult to insert and may cause higher rate of expulsion because of their frame, a copper IUD seems more adequate as it has a lower expulsion rate.
Women with a high menstrual blood loss are better off with a frameless hormone-releasing IUD.

3. The frameless LNG IUS (FibroPlant™-LNG)

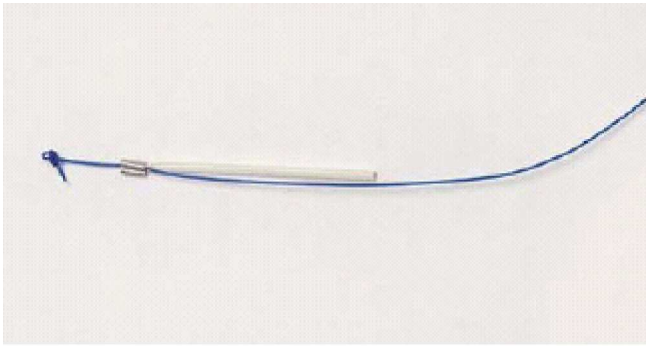

Figure 9. Fibroplant™-LNG-IUS. [40]

The frameless LNG intrauterine system (IUS) has been developed from the frameless GyneFix® device and consists of two components: a 3 cm long coaxial fibrous delivery system, which delivers 14µg/day of LNG for a minimum of five years, and the conventionial anchoring system used with the frameless GyneFix® IUD (see figures 5, 6).

The fribrous delivery system is attached to the anchoring system by means of a stainless steel clip at the upper end of the fiber that is visible on ultrasound, to allow allocation of the system in the uterine cavity.

The results of clinical studies conducted with the frameless LNG-IUS suggest that the system is safe, well tolerated and effective as contraceptive. [41]

The occurrence of hormonal side effects has been low due to the low systemic absorption of the drug. The frameless LNG-IUS is suitable for both contraception and the treatment of gynaecological conditions such as menorrhagia and dysmenorrhea. [42]

The two-component system is extremely simple and women-friendly, adapting to cavities of most sizes and shapes, which is considered one of the main advantages of this new intrauterine LNG-delivery system.

Chapter 4. Judgements against IUDs

When women hear about IUDs and IUSs all of them know the disadvantages related to the use of these IUDS and IUSs: pain, excess bleeding, minimal safety, infections.
In the early years of IUDs, these disadvantages really were a problem. As it is mentioned above, most IUDs (see figure 1) had a large expulsion rate as their shape didn't adapt to the uterine cavity, with the consequence that women could "feel" the IUD in situ and it caused pain.
But in recent years, a lot has changed. New inventions after years of research offered solutions to these serious complaints. Like the Gynefix®-invention which is a frameless and non-rigid device and which can easily adapt to the changing size of the uterine cavity and has a lower expulsion rate.
Before, the general belief was that all of these IUDs cause more menstrual blood loss (MBL).(42)
In fact, further research with Cu-devices showed that women using a framed Cu-IUD do have an increased MBL compared to women not using any IUD. (43)
But with the invention of GyneFix®, the unfavourable atmosphere around IUDs and IUSs definitely changed. Dr. Wildemeersch, the inventor of Gynefix®, proved that the MBL didn't increase while using this specific anchoring device.(44) With the hormone-releasing variant of GyneFix®, the LNG-Fibroplant™ IUS, the MBL even decreases.(45)
The MBL can be reduced by reducing the surface area of the foreign body inserted into the uterus wall and can be reduced even more by adding levonorgestrel to that foreign body.

A reassessment of the risk of pelvic inflammatory disease often attributable to an intrauterine device suggested that the estimated risk was low, only 0.15 even in regions where the prevalence of sexual transmitted infections is high. (19)

Chapter 5. Conclusion

New developments in the field of intrauterine drug delivery have the potential to challenge the oral contraceptive pill and to revolutionize the use of intrauterine contraception in regions where current use of IUDs is extremely low. They can help reduce the unacceptable high number of unintended pregnancies and induced abortions in many countries.

Furthermore, the 'frameless' IUS has been shown to be highly effective for emergency contraception and for immediate post-abortal insertion. The long lifespan of the IUS could constitute a cost-effective reversible alternative to irreversible female sterilization.[26]

For what the safety of IUDs may concern, Table 2 on the following page shows the difference in efficiency of several contraception methods these days.

	% of women experiencing an unintended pregnancy within the first year of use		% of women continuing use at one year
Method	Typical use	Perfect use	
Chance	85	85	
Spermicides	26	6	40
Periodic abstinence	25	1-9	63
Cervical cap	20-40	9-26	42-56
Sponge	20-40	9-20	42-56
Diaphragm	20	6	56
Withdrawal	19	4	
Condom			
- Female	21	5	56
- Male	14	3	61
Pill	5		
- Progestin only		0.5	
- Combined		0.1	
IUD*			
- Copper T380A	0.8	0.6	78
- LNg 20**	0.1	0.1	81
Depo-Provera	0.3	0.3	70
Female sterilisation	0.5	0.5	100
Male sterilization	0.15	0.10	100

*Failure rates with the 'frameless' GyneFix® IUD (not included in the table) are lower than with the TCu380A IUD. **Include the Mirena® and Femilis™ intrauterine systems.

Table 2. Percentage of women experiencing an unintended pregnancy during the first year of typical use* and the first year of perfect use** of contraception and the percentage continuing use at the end of the first year (US).
**Failure rates during typical use* show how effective the different methods are during actual use (including inconsistent *or* incorrect use)
***Failure rates during perfect use* show how effective methods can be, where perfect use is defined as following the directions of use [46]

Intrauterine contraception is the most cost-effective and reversible method of what contraception has to offer these days. Modern high-load copper IUDs are very effective (i.e., efficacy is now close to 100%) when compared with other birth control methods.

So in general, it can be concluded that the occurrence of the "well-known" disadvantages of IUDs highly decreased with the invention of the Gynefix® IUD and the LNG-Fibroplant™ IUS.

It is now just a matter of getting this valuable information to the women needing this kind of contraception and to convince them of the advantages compared to what their general belief says.

Part II.

Granting of the Gynefix® US Patent

Chapter 1. The patent system

A patent is a temporary government-granted monopoly right on something made by an inventor. A utility patent gives a 20-year right to stop anyone from practicing the protected invention.

The historical purpose of the patent system was to encourage the development of new inventions, and in particular, to encourage the disclosure of those new inventions. A temporary monopoly on the commercial use of the invention provides a remedy for the inventors' possible hesitation to reveal the details of the invention, and so acts as an incentive to disclose the details of the invention.

When the patent is published with all the details of the invention, other people can learn of its' existence. They might then be inspired to think up enhancements or alternatives to the patented invention.

Because a patent is a right to exclude others from practicing an invention, the patent system affects everyone. You cannot choose to ignore patents or decline to participate in the system. Even if you are developing something by yourself, without paying any attention to what the rest of the world is doing, you could still be stopped by someone who holds a patent on what you are developing.

Applying for patents can be very expensive, especially when doing so in multiple countries. This makes a patent system the most useful for larger companies. The most popular reason to apply for patents is the possibility to earn licensing money, although in some fields (particularly pharmaceuticals) exclusivity is the most important reason. (47,48)

Chapter 2. Title 35 of the United States Code (Congress, 19th of July 1952)

In the US, a patent for an invention is the grant of a property right to the inventor, issued by the United States Patent and Trademark Office. Generally, the term of a new patent is 20 years from the date on which the application for the patent was filed in the United States.

The right conferred by the patent grant is, in the language of the statute and of the grant itself, “the right to exclude others from making, using, offering for sale, or selling” the invention in the United States or “importing” the invention into the United States. What is granted is not the right to make, use, offer for sale, sell or import, but the right to exclude others from making, using, offering for sale, selling or importing the invention.

Utility patents may be granted to anyone who invents or discovers any new and useful process, machine, article of manufacture, or composition of matter, or any new and useful improvement thereof.

The Constitution of the United States gives Congress the power to enact laws relating to patents (art I, section 8). Under this power Congress has from time to time enacted various laws relating to patents. The first patent law was enacted in 1790. The patent laws underwent a general revision which was enacted July 19, 1952, and which came into effect January 1, 1953. It is codified in Title 35, United States Code.[48]

Chapter 3. Claims of the Gynefix® US patent [49]

The PCT application PCT/BE90/00038 (filed on 3rd of July 1990) for the Gynefix®-invention (see figure 5, 6) was filed in the USA on **22nd of November 1991**, which is the date the US attorney, assigned by the inventor, requested an examination of the PCT application under 35USC section 371, subsection f.

The inventor claimed the following to be patented:

1) A device for fixing a contraceptive device to the wall of a uterus, said device consisting of:
a) a tread of non-biodegradable material, designed to be attached to the contraceptive device and
b) a retaining member implantable in the wall of the uterus and integral with the thread, characterized in that the retaining member implantable in the wall of the uterus consists of a permanent element, of non-biodegradable material, and a temporary element, of biodegradable material, the temporary element temporarily conferring to the implantable retaining member greater resistance to pulling out of the uterine wall than that of the permanent element alone.

2) A device according to claim 1, characterized in that the temporary element, of biodegradable material, of the implantable retaining member is held on the thread by the permanent element, of non-biodegradable material, of the implantable retaining member.

3) A device according to claim 1, characterized in that the permanent element, of non-biodegradable material, is buried in the temporary element, of biodegradable material, of the implantable retaining member.

4) A device according to claim 1, characterized in that the retaining member implantable in the tissue of the uterus, is generally pointed in form to facilitate its penetration into the wall of the uterus.

5) A device according to claim 1, characterized in that the element of biodegradable material of the retaining member implantable in the wall of the uterus constitutes the major part of the size of the implantable retaining member, is pointed in shape and is pierced by a channel opening in the upper part of the point through which the tread passes, and in that a deformation in the thread, constituting the permanent element of the implantable retaining member and formed beyond the channel at the opposite end of the thread from the contraceptive device, also ensures that the element of biodegradable material is held on the thread.

6) A device according to claim 1, characterized in that the deformation in the thread, constituting the permanent element of the implantable retaining member, is smaller in volume and of generally spherical form to allow its withdrawal, under the effect of sufficient pulling, from the wall of the uterus without damaging the latter.

7) A device according to claim 1, characterized in that the deformation in the thread constituting the permanent element of the implantable retaining member, is a knot in the thread.

8) A device according to any one of claims 1, 2, 3, 4, 5, 6 or 7, characterized in that the temporarily element of biodegradable material of the implantable retaining member comprises, in the area thereof remote from the point, means for receiving the end of a needle, with a view to its implantation in the wall of the uterus.

Chapter 4. First rejection (49)

On **17th of June 1992** the US attorney received an answer from the examiner that the US application nº 07/777.365 for an US Patent on the Gynefix®-invention had been examined with the result that all claims (1-8) were **rejected** because of 3 reasons:

1. The format of the application document is not correct:

The claims 1 to 8 were objected under 35 U.S.C. section 112, first paragraph, as failing to provide an adequate written description of the invention, failing to adequate teach how to use the invention and failing to present a best mode of carrying out the invention.

→ Response from the inventor and his US attorney

The format of the application has been changed as requested for an USA Patent application, which seemed to be different than the format for a PCT Patent application.

2. An undetailed description of biodegradable components

Claims 1 to 8 were objected under 35 U.S.C. section 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. In claims 1 to 8 it is not clear as to what type of materials is referred. In claim 1, line 2, "consisting of" is construed as including only those structural elements recited in claim 1. In claims 1 to 8 it is not clear as to how the retaining member is a permanent element.

→ Response from the inventor and his US attorney

A document from a company specialized in biodegradable materials, Birmingham Polymers Inc., Birmingham, Alabama was added to the inventors' response. This in order to convince the examiner that the types of biodegradable materials and non-biodegradable materials, suitable for the use in this claimed invention, are known to those of ordinary skill in the art and do not need to be more fully described.
The document discloses a range of commercially available biodegradable components. The inventor also referred to U.S. Patent nº 3,888,975 belonging to Ramwell which discloses the use of a bioerodable polymer. Non-biodegradable materials and intrauterine devices formed thereof are also shown by the prior art (U.S. Patent nº 3,598,115 belonging to Horne and nº 3, 954,103 belonging to Garcia-Roel et al.).

3. A prior art matter

Claims 1 to 8 were rejected under 35 U.S.C. section 102 (b) as being clearly anticipated by Dirk Wildemeersch US Patent 4,721,105.

→ Response from the inventor and his US attorney

The prior art rejection is incorrect as the former Wildemeersch US Patent 4,721,105 does not disclose a retaining member formed of both a permanent element and a temporary element. Wildemeersch US Patent 4,721,105 discloses rather a retaining member and a thread which are both made entirely of biodegradable or of non-biodegradable material. A retaining member made partly of biodegradable and partly of non-biodegradable material and a thread made of non-biodegradable material as claimed in this application, increases the efficiency of the retaining member during the post-partum period when the uterine tissue is poorly resistant.

Wildemeersch US Patent 4,721,105 does not disclose or suggest providing the retaining member with two such elements.

The inventor of this application thus concluded that claims 1 to 8 are patentable over Wildemeersch US Patent 4,721,105.

Chapter 5. Second rejection (49)

After informing the examiner of the inventors' responses as discussed in the previous chapter, the US attorney received an answer from the examiner on the **16th of December 1992** saying that claims 1 to 8 of US Patent application nº 07/777.365 were **rejected** because of the following reason:

1. A prior art matter

Claims 1 to 8 had been rejected under 35 U.S.C. section 102 (b) as they were being anticipated by Wildemeersch Belgian Patent nº 899,286.

→ Response of the inventor

Wildemeersch Belgian Patent nº 888,286 is issued from the Belgian Application nº 212,661.
Wildemeersch US Patent nº 4,721,105 claims foreign priority of this Belgian application and the disclosures of Wildemeersch US Patent and Wildemeersch Belgian Patent are similar.
Knowing that the previous rejection of these claims under 35 U.S.C. section 102(b) over Wildemeersch US Patent nº 4,721,105 (see prior art matter on the 17th of June 1992) has been withdrawn, the inventor concluded that this is also relevant to Wildemeersch Belgian Patent nº 888, 286.

Chapter 6. Third rejection (49)

After informing the examiner of the inventors' responses as discussed in the previous chapter, the US attorney received an answer from the examiner on the **17th of May 1993** saying that claims 1 to 4 and claims 6 to 8 of US Patent application nº 07/777.365 were **rejected** and claim 5 was objected to because of the following reason:

1. Prior art matter I

Claim 1 was rejected under 35 U.S.C. section 102(b) as being anticipated by Gainutdinova US Patent nº 4,807,610. Gainutdinova discloses a device for fixing a contraceptive device to the wall of a uterus, consisting of a thread and a retaining member that includes a permanent element that is made of a non-biodegradable material and a temporary element made of biodegradable material (a layer that can dissolve).

→ Response of the inventor

The examiner states that Gainutdinova US Patent nº 4,807,610 discloses a device for fixing a contraceptive device to the wall of the uterus which is quite different of what is actually mentioned in this patent: there is no fixation to the wall of a uterus at all. The drawing clearly shows the intrauterine device itself, without any device for fixing it to the wall of a uterus. This intrauterine device has a T-shape which allows it to be kept inside a uterus.

How this inventions functions, can be deduced from the following parts of the description:

> - column 1 line 41-42: ' *It is therefore an objective of the invention to reduce* (note: not to prevent) *expulsion of the device*'.
> - column 1 line 35-38: '*The foresaid known device is characterized by the fact that the coil made from silver-based copper wire adds to the weight of the entire device, thus enhancing the danger of expulsion*'.
> - column 1 line 64-69: '*Thus, provision of the coil base made from an elastic polymer material in all the embodiments mentioned above render the entire device light in weight ...*'

So, reducing the expulsion rate of the intrauterine device is obtained not by fixing it to the wall of the uterus (what would eliminate any risk of expulsion), but by rendering the intrauterine device itself light in weight (see also column 2 line 55-57).

The examiner also states that the device (as mentioned in Gainutdinova US Patent nº 4,807,610) consists of a thread. This thread is announced in Gainutdinova US Patent nº 4,807,610 in column 2 line 16-17 as having for purpose a '*dynamic monitoring of the IUD while in the uterine cavity*'. It is not a part of a device for fixing the intrauterine contraceptive device to the wall of a uterus.

On the contrary, the thread mentioned in the Gainutdinova US Patent corresponds to the tail or string in the Horne US Patent nº 3,598,115, as explained in column 2 line 56-57 of the Horne Patent: 'The tail extends through the cervix into the vagina and is used for removing the device when desired'. So this monitoring or removing function of the thread is quite the contrary of any fixing function.

The examiner also states that the device (as mentioned in Gainutdinova US Patent nº 4,807,610) contains, besides that thread, a retaining member that consists of a permanent element that is made of a non-biodegradable material and a temporary element made of a biodegradable material. From the description (column 2 lines 4-9 and column 2 lines 21-34) and the drawings in the Gainutdinova US Patent nº 4,807,610) appears that the element which is made of the permanent element and the temporary element constitutes the coil which is not a retaining member, but, in fact, is the active element of a T-shaped intrauterine device, such intrauterine device with a coil being known in the art (see column 1 lines 15-27).

Not a single element mentioned by the examiner is appropriate in the present case. Moreover claim 1 of the present application claims that the retaining member is implantable in the tissue of the uterus and is integral with the thread, what has not even been considered by the examiner.
So rejection of claim 1 under 35 U.S.C. section 102(b) seemed not appropriate in the presence of Gainutdinova US Patent nº 4,807,610.

2. Prior art matter II

Claims 2 to 4 and 6 to 8 were rejected under 35 U.S.C. section 103 as being not patentable over Gainutdinova US Patent nº 4,807,610 in view of Horne US Patent nº 3,598,115. Gainutdinova discloses a device for fixing a contraceptive to the walls of the uterus. However, Gainutdinova does not disclose the temporary element held on the thread by the permanent element, the retaining member being pointed, or the thread being in a knot.

Horne discloses a device for fixing a contraceptive to the walls of the uterus comprising a temporary member (a drug) held onto a permanent member by a thread that has a knot therein. The retaining member has a pointed end.

It would have been obvious to one having ordinary skill in the art to incorporate the retaining member and the knot in the thread as disclosed by Horne in order to hold the device in the muscles of the uterus.

→ Response of the inventor

For the reasons explained above, Gainutdinova US Patent nº 4,807,610 does not disclose any device for fixing a contraceptive device to the wall of a uterus, said device having a) a thread, b) a retaining member, implantable in the tissue of the uterus and integral with the thread.

Moreover, Horne US Patent nº 3,598,115 which discloses a device for fixing a contraceptive device to the wall of a uterus, does not disclose, as mentioned by the examiner a device for fixing comprising a temporary member (a drug), held onto a permanent member, by a thread that has a knot therein.

In fact the barb is retained on the shaft by a ball-socket device (see column 2 lines 13-15), while the function of the thread, located at the other end of the shaft and which does in no way cooperate with the barb for fixing the intrauterine device to the wall of a uterus, is explained in column 2 line 56-57. As mentioned above, the function of this thread is quite the contrary of the function of fixing.

With regards to the barb, this Horne Patent is therefore not more relevant than the Wildemeersch US Patent nº 4,721,105, which has been withdrawn of rejection by the examiner previously.

With regards to the thread having a knot therein and used by Horne to remove the intrauterine device from the uterus, nothing would have taught the one having ordinary skill in the art to corporate the barb and the thread having the knot to hold the fixing device in the muscle of the uterus, either by considering the Horne Patent per se (35 U.S.C section 102(b)) or combined with the Gainutdinova Patent (35 U.S.C. section 103).

3. Claim depending on rejected claim

Claim 5 was objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

→ Response of the inventor

Considering the explanation in the two previous points, claim 5 should be accepted without any revising or rewriting.

Chapter 7. Claims accepted (49)

On the 19th of October 1993 the examiner informs the US attorney that claims 1 to 8 are accepted. The United States Patent number US005303717 has been granted on the 19th of April 1994, for a period of 17 year.

Chapter 8. Conclusion

In the present case, the examiner seems not to have a conscientious approach to his work, which causes disadvantages for the inventor as it results in avoidable considerable expenses. The second and third rejections could have been avoided by the examiner.

Part III.

Jurisdiction

Chapter 1. IPC Classification of the Gynefix® Patent (50)

The Gynefix® patent publication number WO91/00714 received the following IPC classification number: A61 F6/14.

A61 F6 stands for a subclass of contraceptive devices, pessaries and applicators thereof; A61 F6/14 classifies the contraceptive devices for females of intrauterine type.

In the following part of this chapter, whenever is referred to 'this type of inventions' with an (*), this refers to contraceptive inventions, like Gynefix®.

Chapter 2. Patentability

From the point of view of the European Patent Convention, an invention is patentable if it is accepted under art 52 to 57. [51]

> European patents shall be granted for any inventions which are susceptible of industrial application, which are new and which involve an inventive step. (art.52(1)).
>
> Within de meaning of paragraph 1, the following in particular shall not be regarded as inventions: discoveries, scientific theories and mathematical methods (art.52(2)).
>
> The provisions of paragraph 2 shall exclude patentability of the subject-matter or activities referred to in that provision only to the extent to which a European patent application or European patent relates to such subject-matter or activities as such (art.53(3)).
>
> Methods for treatment of the human or animal body by surgery or therapy and diagnostic methods practised on the human or animal body shall not be regarded as inventions which are susceptible of industrial application within the meaning of paragraph 1. This provision shall not apply to products, in particular substances or compositions, for use in any of these methods (art.52(4)).
>
> European patents shall not be granted in respect of: inventions of which the publication or exploitation would be contrary to "ordre public" or morality, provided that the exploitation shall not be deemed to be so contrary merely because it is prohibited by law or regulation in some or all of the Contracting States (art.53(a)).

An invention shall be considered to be new if it does not form part of the state of the art (art 54(1)).

The state of the art shall be held to comprise everything made available to the public by means of a written or oral description, by use, or in any other way, before the date of filing of the European patent application (art. 54(2)).

An invention shall be considered as involving an inventive step if, having regard to the state of the art, it is not obvious to a person skilled in the art (art.56).

An invention shall be considered as susceptible of industrial application if it can be made or used in any kind of industry, including agriculture (art.57). [49]

Now, the Gynefix® IUD described in the Gynefix® patent (WO91/00714) seemed to have proved it's

- novelty compared to the state of the art (art 54): thread, knot and the combination of a permanent and temporarily element.
- inventive step as it wasn't obvious for a person skilled in the art (art 56): framed IUD versus frameless IUD.
- industrial application as it can be used in any kind of industry (art 57): pharmaceutical and medical industry.

It wasn't excluded under art 52 (2, 3, 4) and art 55, and it didn't form part of any exception mentioned in art 53.

It also has a technical nature, i.e. it does solve a technical problem in order to be patentable under art 52 EPC in preventing expulsion by implanting the device with a knot in the uterus wall. Thus nothing chemical is of importance for patentability, as might be thought, as there are Cu-cylinders present. It is rather a mechanical/technical invention.

In general 'this type of inventions' (*) don't have many problems with patentability. But in the following 2 cases of the Board of Appeal of the European Patent Office, the patentability of two specific contraceptive inventions is being discussed. Even when they proved to be new and have an inventive step, they weren't considered patentable under the European Patent Convention.

1. Combination contraceptive method with therapeutic method

a. Relevant law

Art 52.(1) and (4) of the European Patent Convention (see above).

b. Relevant Jurisdiction (52)

Case **T 144/83** of the Board of Appeal of the European Patent Office**:** Therapy relates to the treatment of a disease in general or to a curative treatment in the narrow sense as well as the alleviation of the symptoms of pain and suffering.

Cases **T 19/86**, **T 290/86**, **T 438/91** and **T 820/92** of the Board of Appeal of the European Patent Office**:** A prophylactic treatment, aimed at maintaining health by preventing ill effects that would otherwise arise, amounts to a method for treatment by therapy as referred to in art. 52(4) EPC.

Case **G 5/83** of the Board of Appeal of the European Patent Office**:** Therapy is not limited to treatments which restore health by curing diseases which have already arisen.

Case **T 24/91** of the Board of Appeal of the European Patent Office refers to therapy as any treatment which is designed to cure, alleviate, remove or lessen the symptoms of, or prevent or reduce the possibility of contracting any disorder or malfunction of the human body.

c. Case T 820/92 of the Board of Appeal of the European Patent Office (52)

In **T 820/92** (OJ 1995, 113) a claimed invention consisting of a contraceptive method involving a therapeutic step was excluded from patentability under art 52(4).

The treatment of the female mammal with a given effective amount of an LHRH composition was carried out to produce the desired contraceptive effect. The concurrent treatment with the oestrogenic and progestational steroids was not to produce any contraceptive effect but as a treatment to avoid side-effects which would otherwise occur as a result of the use of the LHRH composition. The latter step, therefore, was a treatment by therapy within the meaning of art. 52(4) EPC.

Even though the applicant objected that therapy was not the subject of the claims, and even though the method claims were directed to the prevention of pregnancy and not to a therapeutic application, the board noted the following:

> In the case of a method involving the administration of two or more substances, the question for the purposes of art. 52(4) EPC was not whether the main or even the only reason for carrying out the whole of the claimed method was non-therapeutic.
> Rather, a method claim fell under the prohibition of art. 52(4) EPC merely if the purpose of the administration of one of the substances was a treatment by therapy, and the administration of this substance was a feature of the claim.

d. Compared to the Gynefix® invention

The Gynefix®-IUD is not at all related to therapy. The only goal it has is preventing pregnancy which is by the Board of Appeal of the European Patent Office not considered as a disease, disorder or malfunction, but as a natural circumstance *(Case Law T81/84).* Moreover, pregnancy is not an illness and therefore its prevention is not in ***general*** therapeutic according to art 52(4). *(Case Law, T 74/93)*

There are no chemicals, which could have a therapeutic effect involved in the Gynefix®-IUD.

2. Contraceptive cream

a. Relevant law

Art 57. of the European Patent Convention (see above).

b. Relevant Jurisdiction (52)

Case **T144/83** of the Board of Appeal of the European Patent Office: the notion of industry implies that an activity is carried out continuously, independently and for financial gain.

c. Case T 74/93 of the Board of Appeal of the European Patent Office (52)

In **T 74/93** (OJ 1995, 712), the claimed invention is related to alicyclic compounds and their contraceptive use. The product claims and a claim for the process of preparation of a contraceptive composition by formulating the claimed compounds with a non-toxic carrier were not objected to. However, the application was refused by the examining division because claim 5, which was directed to the use of a contraceptive composition (eg a cream) comprising these compounds for applying to the cervix of a female capable of conception, was not susceptible of industrial application as required by art. 57 EPC in so far as the compound was to be applied to the cervix of a human female.
Such use was regarded as purely personal use, carried out in private by women themselves. There was no industry which offered women the service of applying the compound for them.

In respect of the allowability of claim 5, the inventor objected:

> The use of this contraceptive is industrially applicable because the application of a contraceptive cream could be a paid-for service, for example when applied by a prostitute charging her client a price which included a contraceptive, or by a nurse applying a contraceptive to a woman who was disabled in a way which did not allow her to apply the contraceptive herself.
>
> It did not matter whether these uses were small-scale, since there was no requirement in Article 57 EPC for an industry to be of any particular size. Nor did it state that private use could not be commercial. "Private" did not mean "non-commercial".
>
> …
>
> Many inventions in the field of daily needs were used privately and their patentability should not be restricted. Finally, it was not required for an industrial use to be already known; industrial uses which might be created by the alleged invention in the future should also be taken in consideration.

The answer of the board was as follows:

> The question is not whether a prostitute's profession is an industry, but whether the application by a prostitute of a contraceptive composition to the cervix is part of an industry. This is not the case. The application of a contraceptive composition to the cervix as claimed is not part the business relationship between a prostitute and her client, and the contract between them does not cover the question of which means of contraception she may apply to herself.
>
> She has the freedom and responsibility to decide which one to choose, taking into consideration factors such as tolerance and reliability. This holds true at least as long as the client is not affected.
> If the prostitute applied contraceptive means to her client, their use might become part of the business relationship. As long as she applies them to herself and protects herself outside her contact with the client, the client is in no way involved and the application remains in the private and personal sphere of the prostitute.
> A prostitute may have a professional interest in not becoming pregnant in order to remain able to pursue her profession. This is, however, neither her only nor her predominant interest in using a contraceptive. The prostitute has a serious interest in not becoming pregnant from a client for purely private and personal reasons, because this could affect her future life to a much higher degree than the temporary inability to practice.

Also, a pregnancy arising from a non-professional relationship could damage her professional perspectives. Nevertheless, the use of a contraceptive in a private relationship could hardly be regarded as being of an industrial character. This shows that the mere motive for using a contraceptive is of minor importance for the question of industrial application.

The example of the contraceptive cream being applied to a disabled person by a nurse is different as someone else is involved in the application. The fact that this person acts professionally is not sufficient to make the application of the contraceptive an industrial activity. The nurse doesn't offer to apply a contraceptive cream to the disabled person as an industry but helps to satisfy the patients' strictly personal needs. It follows from this that the nature of the activity is not changed by the fact that it is not exercised by the disabled woman herself but by her assistant in acting according to her instructions.

Good to know: In order for this invention to be patented, claim 5 had to be deleted. So the contraceptive cream an sich is patented but not the method of applying this cream.

d. Compared to Gynefix®

The Gynefix®-IUD is susceptible of industrial application and there has not been any doubt of excluding this invention of patentability under art 57 because "inserting" the IUD is a personal and private activity. There is no other way of inserting this IUD correctly without the help and the background of a trained gynaecologist.

Part IV.

Conclusion

On national, European and international level the granting of the Gynefix® (commercial name of the invention) caused no severe problems, except the granting of the US Patent. What the inventor claimed to be patented was rejected 3 times by the examiner which led to extra costs which could after all have been avoided.

The importance of this invention is that it delivers a safe alternative to our society for regular contraception.
Who nowadays wished to prevent an undesired pregnancy can choose a safe device without any hormones, implanted locally without any inconvenience, without causing excess bleeding and without having to think about contraception for the following 5 years.
With Gynefix® there are no such disadvantages as a higher risk to have breast cancer, venous thromboembolism, haemostasis or myocardial infarct as is proven with the use of oral contraception as the pill.

It is the first intrauterine device that is hanging from the uterus wall due to a knot implanted in the wall. This significantly lowers the expulsion rate, compared to the prior art.

The goal of the inventor to help prevent undesired pregnancies is reached, theoretically and legally.

Part V.

Extra

Commercial succes of the Gynefix® IUD

When asked if this invention has been a commercial success this far, the inventor of Gynefix®, Prof. Dr. Dirk Wildemeersch, rather had to give a negative answer.
To start with, as good and efficient as this invention might be, once it is commercialized, it is only money that counts. It seems that pharmaceutical companies can't make enough money from these copper-IUDs, so they don't have budget enough to set up an important promotion campaign.
Then still, IUDs that release hormones have more success as they are often used to reduce the menstrual bleeding and as a treatment for several diseases. (53)

Apparently the oral contraceptive business can make better money and so has more funding for an important promotion campaign than the copper-IUDs. In this way they keep on being distributed commercially even though it has scientifically been proven that oral contraception like the pill has serious side effects and risks (see chapter 1. Title 3. Oral contraception). Even social security returns around 75% of the cost of the pill for women under the age of 21. (54)

The cost to insert Gynefix® which can be used for a period of 5 year:

- is around 100€ for the IUD itself + around 40€ for the doctors fee to insert the IUD = a total of **140€** per 5 year.

This compared to the cost of the pill over a period of 5 year:

- an average of 15€ per 3 months for the pill itself + around 20€ per 3 months for the doctors fee to give a prescription → multiplied by 20 to reach a total of 60 months (or 5 years) = a total of **700€** per 5 year.

Conclusion: The pharmaceutical companies distributing the pill are making good money; women using this contraceptive are risking their health.

Money versus Health?!

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