REGISTERED MAIL
The President of the European
Court of Human Rights
European Council
F-67075 Strasbourg Cedex

2.3.2006

Applicant: Dipl.-Ing. Dr. Wassil Nowicky
Margaretenstr. 7, 1040 Vienna, Austria

for: Article 6 of the European Convention on Human Rights

COMPLAINT

AS SET OUT IN ARTICLE 34, EUROPEAN CONVENTION ON HUMAN RIGHTS

Duplicate
64 Exhibits
in single copy

Admissibility of the Complaint

My application for authorisation of the preparation Ukrain as a cancer therapy dated 28 June 1976 was rejected by decision by the Federal Minister of Social Security and Generations dated 25 April 2002, i.e. after 26 years, based on expert reports that were only presented to me together with the decision. This robbed me of the opportunity to submit a statement regarding these expert reports in the proceedings with the Ministry. Had these expert reports been delivered to me – as is called for by law in order to safeguard the right to hearing of parties – before the decision was issued, I would have refuted these negative expert reports with the appropriate argumentation, so that a negative decision would not have been issued. As a result of the procedure by the authority, the evidence at my disposal to refute the spurious argumentation presented by the experts was unlawfully suppressed. Although the Administrative Court, which was subsequently appealed to, as set out below, acknowledges this violation of the right to party hearing as unlawful, it sweeps aside the arguments of the expert Dr. Tittel submitted by me, namely that experimental proof of inter-batch reproducibility had been provided repeatedly, with the argument that in his statement dated 3 May 2002 Dr. Tittel had expressly admitted that it was correct that the chemical structure of the complex mixture was not fully known, interpreting this insignificant fact as a significant deficiency that rehabilitated the omissions and unlawful procedure on the part of the Ministry. This argumentation by the Administrative Court proves to be spurious, however, since Dr. Tittel had explicitly pointed out in this context that although a further structural analysis would be desirable it was not absolutely necessary, since the synthesis was reproducible and the defined specifications guaranteed a reproducible product within narrow limits.

Thereby the Administrative Court fails to comment in any way on why, despite repeated evidence of the significant effect of Ukrain, it could still accept that this cancer therapy remains unauthorised, and why it considers the subordinate formal argument of allegedly (but not factually) inadequate structural clarity as being more important than the life-saving or improving effect of Ukrain. An indication of the omission of this evaluation is provided by the comments on pages 7 and 9 of the Administrative Court ruling: The chemical-pharmaceutical expert Dr. Robert was of the opinion that it had not been proven that the drug was sufficiently characterised, that the planned test methods guaranteed the quality, and that production was reproducible from batch to batch. Since the deficiencies with regard to quality were of a fundamental nature, he had refrained from discussing the individual issues in detail in his expert report, e.g. description and analytical validation of the test methods, suitability of the specifications.

The authority itself justified the omission to deliver the expert report d e c i s i v e for the negative outcome of the procedure to me with the “justification” that it had been omitted because the report by the external expert had not produced any new findings with regard to the assessment of the application for authorisation.

At the same time the Administrative Court itself points out that when handling complaints special skills and experience are required to answer the issues of relevance to the decision, which the authority against which the action is addressed does not itself

have (Finding by the Administrative Court (hereinafter "AdmC Finding"), page 14, par. 3; Exhibit 1).

Precisely this circumstance of limited expert knowledge would, however, have required all the more urgently that I be granted sufficient scope for comment. Instead, the authority denied me this possibility in a clandestine file procedure, and the relevant arguments had to be presented to a court with even less expert knowledge than the relevant authority within the relatively short period granted for filing a complaint with the Administrative Court. The only legal possibility to remediate the unlawful procedure on the part of the Ministry would have been to repeal the negative decision by the authority, granting me broad opportunities to comment, which would also have been accessible for subsequent control. Instead, the Administrative Court itself issued a valuating assessment based on the available spurious arguments.

On 7 June 2002 I filed an objection to this decision with the Administrative Court within the set deadline. This objection was denied in a finding dated 21 November 2005 – after more than 3 years – despite the fact that the authority had been of the opinion that the expert reports had not provided any new findings.

As a result, I feel that my public right to preservation of the party hearing, the lawful judge, a fair procedure, and in accordance with Art. 6 of the Convention on Human Rights has been violated. With the finding by the Administrative Court, all stages of appeal have been exhausted in Austria. With this finding, my right to a fair procedure as set out in Art. 6 of the Convention on Human Rights has been violated, therefore I am appealing to you and filing a complaint within the permissible deadline.

Introduction

With the finding appealed against here, no. 2002/10/0096-8 of 21 November 2005 (Exhibit 1), my application dated 28 June 1976 was denied finally.

Ukrain is produced from *Chelidonium majus L.*, a wild plant that grows without cultivation in the northern hemisphere. This plant, commonly known as greater celandine, has been used as a natural remedy for more than 3500 years.

Ukrain ampoules contain an alkaloid fraction obtained from the celandine root in water-soluble form. Water solubility is achieved using a patented method, whereby the alkaloid fraction that is not water-soluble initially is converted into a water-soluble form through treatment with hydrochloric acid in a solution containing thiotepa. The solution in Ukrain ampoules does not contain thiotepa (analytically proven, residue limit is specified).

Conventional cytostatic agents have a therapeutic index in the range of 1.2-1.8 (the therapeutic index is the difference between effective and toxic dose) and they are – as is known – highly toxic with numerous side effects. The **therapeutic index for UKRAIN is 1250**, the preparation is very tolerable. Its effectiveness and safety have been demonstrated by numerous experimental and clinical studies.

The quality of the product and its reproducibility are guaranteed.

Facts of the Case

Once the Austrian Cancer Research Institute had determined that Ukrain was effective against cancer cells and hundreds of times less toxic than thiotepa, an application was filed on 28 June 1976 for authorisation of Ukrain in Austria as a drug fur use in therapy-refractory cancer or in patients where all other available therapies (chemotherapy and/or radiation) were contraindicated. **The application for authorisation is assessable in accordance with the Pharmaceuticals Code valid at that time** (Exhibit 2). An extract of the celandine root is used in the production of Ukrain. This root is well known in literature, and a monograph on the quality was prepared. The substance thiotepa, which is used in the patented process, is monographed in the British Pharmacopoeia and authorised internationally as a cytostatic agent. Ukrain is significantly less toxic than these two substances, and is well tolerated – even the experts agreed in this point.

What is even more important, however, is that Ukrain is effective against malignant tumours – this was demonstrated in many experiments *in vitro* (e.g. by the National Cancer Institute, USA, Exhibit 3), *in vivo* (Miami University, USA, Exhibit 4), as well as numerous clinical trials, including randomised studies (University of Kiev, Ukraine, Exhibit 5; University of Donezk, Ukraine, Exhibit 6) and studies conducted in compliance with GCP (University of Ulm, Germany, Exhibits 7 and 8).

As early as 1983, at the 13th International Chemotherapy Congress in Vienna, I already reported on 100 cases of therapy-refractory patients (Exhibit 9), in which treatment with Ukrain achieved full remission (Exhibit 10a, Prof. Wodniansky, Austria), partial remission (Exhibit 10b, Prof. Judmaier, Austria), or even just an improvement in general health (Exhibit 10c, Ludwig Bolzmann Institute for Clinical Oncology, Austria), and in 1986 I submitted 450 case reports (including about 80% from Austrian clinics) to the Federal Ministry of Health. Despite this, my preparation was not authorised in Austria. In contrast, the American preparation Taxol was authorised in Austria, which was not even the country of origin, as the first country in the world, based on only 17 case reports.

After the publication of Ukrain at this renowned international congress, numerous researchers from all over the world got in touch and displayed in interest in conducting research with Ukrain. So far, more than 250 researchers at more than 60 universities in 22 countries have worked with Ukrain and confirmed its effect, and more than 200 papers have been published in medical journals. Ukrain has also been the subject of many dissertations (Exhibit 11). All these papers have contributed significantly towards understanding the mechanisms of action of Ukrain, of which the following have been decoded to date:

- rapid accumulation in malignant cells and tissues with dose-dependent inhibition of DNA, RNA and protein synthesis and growth inhibition between 50% and 100%, which turns into a cytolytic effect with reduction of the total cell mass at higher concentrations; the yellow-orange auto-fluorescence of Ukrain under UV light allows the tumour tissue or individual cancer cells to be visualised (proven by research conducted by The National Cancer Institute, Bethesda, USA; Division of Basic Sciences, Faculty of Medicine, Memorial University of Newfoundland, Canada; Ukrainian Anti-Cancer Institute, Vienna, Austria; Institute of Biochemistry, National Academy of Sciences, Grodno, Belarus)

- inhibition of tubulin polymerisation with subsequent accumulation of the cancer cells in the G2/M phase (proven by research conducted by the Department of Dermatology, University of Rochester School of Medicine and Dentistry, USA; Department of General, Visceral and Transplantation Surgery, University of Ulm, Germany)
- Ukrain causes depolarisation of the mitochondrial membrane potential with reduction of the oxygen uptake and activation of kaspases, which ultimately results in apoptotic cell death in the malignant cells (proven by research conducted by the University of Tübingen, Germany; Federal Institute for Experimental Pharmacological and Balneological Testing, Vienna, Austria)
- Ukrain has anti-angiogenetic properties (proven by research conducted by he Institute for Biochemistry and Molecular Cell Biology, University of Vienna, Austria)
- Ukrain increases the sensitivity of the cancer cells for ionising radiation and protects normal human fibroblasts from radio-induced damage (proven by research conducted by the Institute of Radiobiology, German Armed Forces Medical Academy, Germany)
- Ukrain inhibits the growth and metastasing of various tumours and down-regulates SPARC (Secreted Protein Acidic and Rich in Cysteine) – a protein important for the aggressiveness, matrix decomposition and distant reproduction of malignant cells (proven by research conducted by the Ukrainian Research Institute of Oncology and Radiology, Kiev, Ukraine; University of Milan, Italy; Ukrainian Anti-Cancer Institute, Vienna, Austria)
- Ukrain stimulates the synthesis of collagen fibres in the tumour, which results in encapsulation of the tumour and separation from the surrounding healthy tissue, as well as improving the results of surgery (proven by research conducted by the Medical Institute, Grodno, Belarus)
- Ukrain is a highly immunomodulating agent and activates the anti-tumour macrophages, increases the monocyte, T-helper cell and NK cell counts, and reduces the number of T suppressors, thus meeting all the requirements for the unspecific family of “modulators of the biological reaction” (proven by research conducted by the University of Miami School of Medicine, Florida, USA; Division of Basic Sciences, Faculty of Medicine, Memorial University of Newfoundland, Canada; Ukrainian Anti-Cancer Institute, Vienna, Austria).

Nonetheless, the experts rhetorically claimed: no proven effect (Finding, pp. 2, 4, 5, 6, 10, 13, 15). A logical question suggests itself: **did the experts ever read the submitted material?**

All the necessary toxicological studies were repeated in compliance with GLP by the Austrian Research Centre Seibersdorf and submitted to the Ministry (“UKRAIN Concentrate”: Acute Intravenous Toxicity with Rats, Exhibit 12; “UKRAIN – Solution for Injection 5 mg/5 ml”: 6-Month Intravenous Toxicity Study with Rabbits, Exhibit 13; “UKRAIN 5 mg Ampoules”: Salmonella typhimurium Reverse Mutation Test, Exhibit

14; “UKRAIN Ampoules”: Micronucleus Test with Mice, Exhibit 15; “UKRAIN Concentrate”: Micronucleus Test with Mice, Exhibit 16; “UKRAIN Concentrate”: Acute Intravenous Toxicity Study with Mice, Exhibit 17; “Intravenous, Intra-arterial, Paravenous and Intramuscular Irritation Study with “UKRAIN – Solution for Injection 5 mg/5 ml” in Rabbits”, Exhibit 18).

Ukrain was authorised in several countries; in the USA and in Australia this preparation has been granted Orphan Drug Status (Exhibit 19).

For all these reasons, I should have been able to expect rapid authorisation. Instead, the Federal Ministry of Health and Consumer Protection denied authorisation on 2 June 1999, because the submitted documentation was regarded as insufficient. (Exhibit 20).

On 26 February 1996, the appealed decision was annulled by the Administrative Court because of unlawfulness due to the violation of procedural rules. (Exhibit 21).

For 30 years now, the Austrian health authority has been making increasingly new demands and thus obstructing the authorisation. With constantly changing legislation, authorisations could be obstructed not only for 30 but for hundreds of years in this manner. However, as is shown in Exhibit 1, my application for authorisation must be processed on the basis of the laws in force in 1976, since the application was filed in 1976.

On 31 October 1997, I requested the relevant authority, the Federal Institute for Chemical and Pharmaceutical Testing, to evaluate the documents resubmitted by me. The expert report by the Federal Institute dated 8 January 1998 (Exhibit 22) took the view that the active substance defined by me, “Ukrain (Complex)” did not even exist. All the synthesis source products (celandine alkaloids) had been detectable as unchanged in the end product; the reaction partner thiotepa was present in polymeric form. (Finding by the Administrative Court, p. 3).

In a letter dated 8.1.1998, the Federal Institute for Chemical and Pharmaceutical Testing, which at the time was subordinate to the regulatory authority, even claimed that I had been granted the patent without justification and openly suggested informing the Patent Office of this fact. Thereby the Federal Institute exceeded its competences significantly.

In my letter dated 9 April 1998, I already asked for answers to the following questions:

“a) I would kindly ask you to inform me of the relevant scientific documents with chemical and physical data, on which this claim is based.

b) With which methods were these tests performed, and how do you explain the fact that Ukrain has completely different effects in vitro, in vivo and toxicologically than the celandine alkaloids and thiotepa?

c) With which methods do you believe that you are able to prove that the reaction partner thiotepa reacts with itself and is present in polymeric form?

d) Which lab analyses allegedly confirm this theoretical expert report, and how, when and by whom were these lab analyses performed?

Based on which scientific data does the Federal Institute claim that the patents for my process were granted without justification? Do you believe it is possible that Patent

Offices all over the world grant patents without examining a process in detail?" (Exhibit 23)

All these questions have remained unanswered to this day.

The negative decision by the Federal Ministry of 25 April 2002, No. 921.726/13-.VI/16/02, was sent to me **together with the expert reports that I had never seen before**.

Moreover, this decision was substantiated by expert reports by experts who were themselves not even clear about whether the observed effect was due to Ukrain or to thiotepa or the celandine alkaloids! (Finding by the Administrative Court, p. 6). A further argument they used was that the structural formula was unclear and therefore reproducibility could not be guaranteed. (Finding by the Administrative Court, pp. 4, 13, 15, 18). This was supposed to be the reason why further examination of the documentation was not required. (Finding by the Administrative Court, p. 17).

On 7 June 2002 I filed an objection to this notification with the Administrative Court within the set deadline.

Meanwhile I have filed a complaint with the European Court of Human Rights.

On 24 February 2005, the EUROPEAN COURT OF HUMAN RIGHTS condemned the Republic of Austria and decided: The Republic of Austria has violated Art. 6 Par. 1 of the European Convention on Human Rights inasmuch as the authorisation procedure was not concluded within a reasonable period of time. (Exhibit 24).

My objection was denied in a finding dated 21 November 2005 – after more than 3 years – despite the fact that the authority had been of the opinion that the expert reports had not provided any new findings. (Exhibit 1).

How is the refusal of authorisation substantiated?

In their statements of 25 November 1997 (Finding p. 2), Univ. Prof. Dr. Eichler and Dr. Pittner clearly stated that at this point in time not a single document credibly documenting a patient benefit from "Ukrain" in accordance with the state of medical art had been available. The use of "Ukrain" as a therapeutic agent outside planned, controlled clinical trials was therefore not justified in accordance with the state of the art (Finding by the Administrative Court, pp. 2, 3, 4). The following facts were not even mentioned by Prof. Eichler and Dr. Pittner:

On 23 June 1993 the Drugs Council at the Federal Ministry of Health, Sports and Consumer Protection approved a clinical study (file no. 21.405/530-II/A/8/93). The Federal Ministry also approved a clinical study to be conducted outside hospitals. In this type of clinical trial, various oncological diseases such as they are encountered in the everyday practice of town and country doctors are to be treated with Ukrain.

"The Office of the Drugs Council informs you that with regard to the submitted study protocols for Ukrain, Expertise No. 558, there are no further formal objections."

The summary of the concluding expertise further states:

"In consideration of all the observations made, it can be said that a clinical trial in Austria can also be approved under certain circumstances, since ***tolerability of the substance is obviously very good****."* (Exhibit 25, page 10).

Many doctors declared that they were willing to participate in this study and reported on their experiences (Exhibit 26). These reports were submitted to the Ministry of Health. They showed that at least a significant improvement in the quality of life could be achieved with Ukrain, even in advanced stages. The doctors were in favour of rapid authorisation of Ukrain for a broad application.

Studies with colorectal carcinoma were conducted abroad – in this case in Ukraine – in accordance with the study protocols approved by the Ministry. The results of the studies were published and submitted to the Federal Ministry (Exhibits 5, 6).

Expert Dr. J.-L. Robert admits that he did not read the submitted documentation, and the other one obviously did not either – how else can it be explained that he is ignoring the submitted documents and simply negating the research work of researchers from all over the world? Instead, the experts issued recommendations not to authorise the preparation Ukrain.

"… From my point of view I can only advise against the authorisation based on the submitted chemical-pharmaceutical documentation." (Expert Report Dr. J.-L. Robert, Exhibit 27)

"Neither the documentation for Part III nor for Part IV would justify authorisation of this substance" (Expert Univ. Prof. Dr. H. Winkler, MD, Exhibit 28)

These statements by the experts are remarkable in several respects: The experts have failed to appreciate their function entirely, they have told the deciding authority what to do instead of studying the facts and presenting a verifiable expert report.

Another expert, Prof. Winkler, does not know which substance – thiotepa or alkaloids – is responsible for the effect of Ukrain (AdmC Finding, p. 6). It is however known that neither thiotepa nor alkaloids have been in use for cancer of the colon. Ukrain does, however, have an anti-tumour effect in colorectal carcinoma – as shown by randomised clinical studies and *in vitro* studies by the NCI (Exhibit 2, 5).

Thereby it would have been so easy to visit the website of the online medical library http://www.ncbi.nlm.nih.gov/entrez/query.fcgi?DB=pubmed
and search for the key words "thiotepa" or "celandine alkaloids".

DDr. Winkler claims: The clinical effectiveness is not proven. (Finding by the Administrative Court, p. 6) In 2005 two British researchers, Edzard Ernst and Katja Schmidt (Universities of Exeter & Plymouth) conducted an independent analysis of the clinical studies with Ukrain. Thereby they used the so-called Jadad Score (this is the Golden Standard for the assessment of clinical studies) and came to the following conclusion:

"Seven trials met our inclusion criteria. Without exception, their findings suggest that Ukrain has curative effects on a range of cancers". (Exhibit 29)

Elsewhere it is claimed that *"The long-term safety is difficult to assess because no animal trials of chronic toxicity with high doses are available. Thereby a potential risk in*

*clinical **long-term use** is difficult to assess, even if the available data for routine parameters did not show any abnormal results."* However, this fully ignores the fact that the application for authorisation was submitted for therapy-refractory cancer patients. It is generally known that virtually **all conventional anti-cancer agents** belong to the group of cytostatic agents and are both **mutagenic** and **carcinogenic** – yet they are nonetheless established as standard therapy in oncology. I must repeat: conventional cytostatic agents have a therapeutic index of 1.2 to 1.8, Ukrain: 1250! For many of these preparations, toxicity studies were not even conducted. Here are just tow examples:

- *"The safety and effectiveness of Mabthera in children has not been studies… Reproduction toxicology studies in the animal model* (Administrative Court Finding, p.2) *were not performed with rituximab. Nor is it known whether the administration of Mabthera to pregnant women can cause damage to the foetus, or whether it affects the reproductive capacity…"* (from the Summary of Product Characteristics for Mabthera, Exhibit 30)
- *"Chromosomal damage, including chromatid breakage, has been produced by gemcitabine in* in vitro *studies… Long-term duration animal studies have not been conducted to evaluate the cancerogenic potential of gemcitabine… The safety of this medicinal product for use in human pregnancy has not been established… Evaluation of experimental animal studies has shown reproductive toxicity, e.g. birth defects or other effects on the development of the embryo or foetus… Gemcitabine has demonstrated teratogenic effects in mice and rabbits at doses of less than 2 mg/m^2…"* (from the Summary of Product Characteristics for gemcitabine – standard drug for cancer of the pancreas. The single dose is 1000 mg/m², Exhibit 31)

Ukrain did not display any toxic effect in the Ames and Micronucleus Test, and other toxicity studies also demonstrated its safety. In experiments with rats and hamsters, Ukrain did not show any embryotoxicity or teratogenicity (Exhibits 32, 33). The submitted data on the chronic toxicity of this preparation, which also included a 6-month study with rabbits and a 6-month study with rats, would normally be absolutely sufficient – were we not talking of Ukrain.

The expert criticises the clinical study performed by the Surgical Department at the University of Ulm and claims that the effectiveness of Ukrain in palliative treatment of pancreatic carcinoma had not been demonstrated (Finding by the Administrative Court, p. 10). Thereby his criticism is mostly difficult to follow and it is clearly refuted in the joint statement by the authors of the Ulm study (Exhibit 34).

We speak of palliative therapy when curative treatment is no longer possible. Cancer of the pancreas is probably the most aggressive carcinoma of all. The life expectation of the patients is very short and they are fighting for every single day. Therefore it is not surprising that the US regulatory authority, the FDA, has authorised a chemotherapeutic agent for palliative treatment of pancreatic carcinoma that extends the survival time by only 12.8 days (!!) – and that is celebrated as a major success (Exhibit 35), even taking the serious side effects into account. The fact that Ukrain prolongs the survival of a similar group of patients by more than 10 months is simply ignored by the Austrian health authority and by the experts.

A serious example of this unfounded criticism: the authors of the study are accused of treating the patients in the three study groups for different lengths of time. Anyone in oncology knows that a therapy can consist of several cycles and that the differences in duration of therapy result quite simply from the fact that the patients in therapy groups B and C (Ukrain monotherapy and Ukrain/gemcitabine) lived significantly longer than the patients in group A (gemcitabine monotherapy): the median survival time in group A was 5 months (which corresponds with the results from other studies) versus more than 10 months in groups B and C (Ukrain monotherapy and Ukrain/gemcitabine).

The above expert report points out that the individual groups differed strongly with regard to various factors. However, three were no statistically significant differences between the individual groups in any of the named parameters. Such fluctuations must be expected with a smaller group size of 30 patients per group. Neither the patient's age nor the patient's gender is of prognostic importance in advance pancreatic carcinoma (Exhibit 34, Prof. Beger).

The expert also demands a double-blind study with placebo (AdmC Finding, p. 5), but as the book "Guidelines for Clinical Studies" literally states, "*no sensible person would ever conceive of comparing cytostatic agents with placebo"* (Exhibit 36).

Yet all these should be the reasons for denying the authorisation of a drug for the treatment of therapy-refractory cancer patients!

Clinical Study

Based on the decision by the Federal Ministry of Health, Sports and Consumer Protection, file no. 21.405/1011 – II/A/8/92 of 4 April 1993, a "clinical trial in hospitals as well as outside hospitals as set out in § 42, Austrian Drugs Act" (Exhibit 25) was ordered. At the initiative of Section Head Dr. Norbert Rozsenich from the Ministry of Science, the protocol for a clinical study was drawn up. However, the Ethics Committee demanded a double-blind study with a placebo-controlled group. The responsible doctor rejected such a study as ethically unacceptable, however, and had to abandon it (Exhibit 37).

No clinic in Austria was prepared to conduct a clinical study, therefore a randomised study based on the protocol approved by the Office of the Drugs Council at the Austrian Ministry of Health was initiated, conducted and published in Ukraine (see Exhibits 5 and 6).

The German government considered it its duty to have a study conducted with Ukrain at its own expense, whereby the advantages of Ukrain were clearly demonstrated in this randomised study. In the latter study it was pointed out in conclusion that "*Ukrain is well tolerated and can also be administered easily in the outpatient sector. Compared with gemcitabine therapy, the survival time is significantly prolonged."*

In order to prevent clinical trials with Ukrain from being conducted, the Ethics Committee and the Ministry of Health demanded so-called double-blind studies with placebo (Exhibit 37, 39). Thereby it was clear from the start that no clinic would be prepared to conduct a clinical trial with cancer patients under such conditions.

The authority was well aware that the demand for a placebo control group had been made for a clinical study planned in Austria, whereupon this clinical study had to be cancelled due to this placebo control group demand, which was unacceptable in every respect.

On the contrary, when doctors wanted to prepare a clinical study with outpatients, unlawful decrees were issued and there were even cases of disciplinary action (Exhibit 40). Nonetheless some doctors refused to be intimidated and continued treating seriously ill patients with Ukrain and reporting their therapy successes to the Ministry of Health. These doctors also requested that Ukrain be authorised as quickly as possible (Exhibit 26).

I would like to comment on the following allegations that are inconsistent with the file and counter to the facts:

"…There was no consistent data establishing a mechanism of action for "Ukrain" in humans…" (AdmC Finding, p. 5, 1st paragraph from top).

It has been shown that Ukrain has a profound immunomodulating and anti-angiogenetic effect in cancer patients (Exhibit 41, 42, 43, 44, 45, 46).

"… Nothing is known about the pharmacokinetics in humans…" (AdmC Finding p. 5, 2nd paragraph from top).

A study on the pharmacokinetics in rats was published in 2000 (Exhibit 47) and a study on human pharmacokinetics was also submitted then (Exhibit 48).

"… As long as there is no detection method for the assumed complex…" (AdmC Finding p. 5, 2nd paragraph from top).

Ukrain can be identified both qualitatively and quantitatively using a simple spectrophotometric measurement (wavelength 210 and 230 nm, Exhibit 49), as well as by means of HPLC (Exhibit 50).

"… Interactions with the pharmacokinetics of other substances were not investigated…" (AdmC Finding p. 5, 2nd paragraph from top).

Interactions with the most important drug classes were investigated and published (Exhibit 51, 52, 53; Exhibit 54, p. 11).

"… There is not a single study of the clinical effectiveness that would prove this within the meaning of a phase III pilot study…" (AdmC Finding, p. 5, 2nd paragraph from top).

509 patients were included in the phase III studies; the results of these studies were evaluated and presented (Exhibit 54, based on 13 sources of literature from the period 1991-1998).

"…The clinical effectiveness has not been shown…" (AdmC Finding, p. 6, 5th paragraph from top).

The successful treatment of more than 500 patients with Ukrain was documented (Exhibit 54, p. 20).

"…Not a single study was conducted and documented in such a way that it can be regarded as a sufficient foundation for authorisation…" (Administrative Court Finding, p. 6, 6th paragraph from top).

In 2005 two British researchers, Edzard Ernst and Katja Schmidt (Universities of Exeter & Plymouth) conducted an independent analysis of the clinical studies with Ukrain. Thereby they used the so-called Jadad Score (this is the Golden Standard for the assessment of clinical studies) and came to the following conclusion:

"Seven trials met our inclusion criteria. Without exception, their findings suggest that Ukrain has curative effects on a range of cancers" (Exhibit 29.

The Austrian Ministry does not accept proof of the clinical effectiveness of Ukrain that was obtained in other countries. As shown by the letter dated 3.9.2004, BMGF-20125/0087-III/B/7/2004, the Federal Ministry states (Exhibit 55):

- that no clinical studies with Ukrain have been approved in Austria
- that there is no import licence for Ukrain from other countries
- that the condition set out in § 12 par. 1 (2), Austrian Drugs Act, is not fulfilled in the case of use of Ukrain in Austria either, because medicinal products to achieve a health improvement are authorised and available in Austria.

With this procedure, the Federal Ministry is robbing 35,000 people who get cancer every year of the opportunity to take Ukrain. 19,000 people die of this disease every year. These 19,000 people were denied their right to health – see Article 25 of Resolution 217 A (III) of 10.12.1948 of the Human Rights.

This example illustrates the violation of my right to a fair procedure as set out in Art. 6 of the Convention on Human Rights.

The Federal Ministry of Transport, Innovation and Technology was aware of the importance of my work. And had to find: "It is therefore incomprehensible on the other hand, why the Austrian health authorities are still sabotaging the authorisation efforts by Dr. Nowicky" (Exhibit 56).

"Inconsistent inter-batch analysis results for the finished product"

The statement by the Federal Institute for Drug Testing of 2 October 2000 claims that *"inconsistent inter-batch analysis results were obtained with regard to identity, content and purity testing of the active substance and the finished product"* (AdmC Finding, p. 4).

I would like to comment on this as follows:

It is absolutely unclear on the basis of which investigations this incomprehensible claim by the Federal Institute was made?

Over the years dozens of batches were produced with documented consistent composition, and – as shown by the reports and data published by doctors and researchers – the same good effect was achieved with every batch. Moreover, 15 batches were delivered to various labs for testing using state-of-the-art methods (mass spectroscopy high performance liquid chromatography, MS-HPLC), whereby batch conformity was determined (Exhibit 57).

However, Dr. Robert does not appear to have studied the documentation with the intensity to be expected from an expert. On page 6 of his expert report in the third paragraph of the 3rd conclusion he writes, for example (Exhibit 27):

"Since the deficiencies with regard to quality are of a fundamental nature, the individual issues are not discussed in detail in this expert report, e.g. description and analytical validation of the test methods, suitability of the specifications."

Even then there were no fundamental deficiencies with regard to quality in my opinion, but rather an accumulation of ambiguities resulting primarily from the controversial structure discussion and non-observance in parts with the EU Guidelines on Quality valid at the time. In the documentation of the year 2000, the validation data was already included for all the relevant analysis methods in the form and partly in the scope required by the relevant ICH Guidelines. All the analysis methods used, whether DC or HPLC, were evidenced by appropriate specimen chromatograms.

Had the expert taken a closer look at the details, he would have had to see that all the analytics fundable to date had been performed in order to guarantee reproducible quality of the product.

The lacking depth of his assessment is shown by the following contradiction:

On page 2, no. 2.2. Part B II, Dr. Robert mentions that the ampoule manufacturer Solvay has a manufacturing licence. Yet in his conclusion on page 6, he writes:

"It is also unclear whether the manufacturer of the ampoules has a valid manufacturing licence…".

Thus the expert negligently suggests to the Austrian regulatory authority that the product could be a medicinal product quasi not legally produced in accordance with GMP.

It must be noted that in 2000 Ukrain was duly produced in accordance with GMP by SOLVAY and released by their Head of Quality Control. This fact had been mentioned in the documentation.

Alkaloids

In his expert report dated 14 March 2002, Prof. Winkler writes:

"The in vitro effect on cell growth is probably due to the free alkaloids contained in Ukrain. However, Ukrain appears to be less effective than untreated alkaloids". (AdmC Finding, p. 9).

If the effect of free alkaloids is as good as or even better than that of Ukrain, as mentioned, then why are these free alkaloids not made available to cancer patients?

Celandine alkaloids are hardly water-soluble, they are used in numerous medicinal products of the cholagoga group and biliary tract treatments, and they also show an effect when administered locally. Since celandine alkaloids are hardly water-soluble, however, all conventional preparations based on these substances are available in oral form or for local administration. The water-solubility of the alkaloids contained in Ukrain increases the preparation's affinity for cancer cells, allows intravenous or intramuscular administration, and avoids the so-called "presystemic elimination" (partial catabolism of

a substance in the liver by enzyme complexes following oral administration, even before the substance can become effective in the target organ). This increases the efficiency of the drug significantly, while at the same time improving tolerability.

Effect

It is said that the effect of Ukrain has not be documented sufficiently. However, this means that an effect has been documented. So where is the limit of "insufficiently"?

The expert writes *"that it is not acceptable to have a preparation in which the presence of the active substance cannot be defined either chemically-pharmaceutically or by means of a bio-assay."* What is this supposed to mean? The chemical reproducibility of Ukrain as well as its stable effect, i.e. the qualitative and quantitative effectiveness in bio-assays, has been confirmed repeatedly in accordance with international standards.

Why did the expert not read, or ignore, the results obtained by Dr. Tittel mentioned earlier, as well as the bio-assay protocol developed by the Ulm group?

They were only looking for excuses not to authorise the drug. But the fact that 250 researchers at 60 universities and research institutions in various countries have demonstrated the effect of Ukrain and confirmed it in 223 publications is once more being ignored by the experts and by the authority. They simply keep repeating rhetorically that no effect has been demonstrated.

It is not clear to the experts and the authority whether the effect of Ukrain is due to thiotepa or to the alkaloids. Various institutes have presented certificates confirming that the end product Ukrain contains water-soluble celandine alkaloids manufactured using a patented process. Thiotepa is not present in the end product.

They further confirm that Ukrain is well tolerated. So why can patients who only have a few days or weeks of life left not at least try out whether the effective and well tolerated drug might help them?

None of my arguments were mentioned

The experts never defined exactly which evidence or measurements I should submit in accordance with the state of the art. They merely pointed out *"that the active substance is insufficiently characterised, i.e. that the identity of Ukrain is unknown."* (AdmC Finding, p. 7). This raises the question of the boundary between "insufficient" and "sufficient".

As already mentioned, Ukrain is produced only from marketable raw materials of perfect pharmacopoeia quality. Some years ago, an attempt was made to prove the structure of Ukrain by converting isolated celandine alkaloids under the patented conditions. These tests and their analytical results were the basis for the patent application. What could not be determined with certainty with the analytical means available at that time was the precise composition of the Ukrain raw material at the end of chemical treatment with thiotepa and hydrochloric acid. However, even then the water-solubility of Ukrain was recognised as decisive for its effectiveness. This water-solubility is the prerequisite for intravenous administration, in contrast to all other products manufactured on the basis of native celandine alkaloids.

SUMMARY

Prof. Dr. Eichler, Prof. Dr. Winkler, Univ. Lecturer Dr. H. Pittner claim that no effect has been demonstrated for the preparation Ukrain (Finding by the Administrative Court, p. 2, 4, 5, 10, 13, 15). Prof. Winkler also claims: "The clinical effectiveness is not proven." (Finding by the Administrative Court, p. 6). The experts unanimously demand that authorisation of this preparation be refused. They also demand that a double-blind study with placebo be conducted (AdmC Finding, p. 6), which is ethically unacceptable for cancer patients.

"Most of the clinical studies are no use. (AdmC Finding, p. 10).

I repeat:

In 2005 two British researchers, Edzard Ernst and Katja Schmidt (Universities of Exeter & Plymouth) conducted an independent analysis of the clinical studies with Ukrain. Thereby they used the so-called Jadad Score (this is the Golden Standard for the assessment of clinical studies) and came to the following conclusion:

"Seven trials met our inclusion criteria. Without exception, their findings suggest that Ukrain has curative effects on a range of cancers". (Exhibit 29)

The two studies with pancreas tumours that have now been presented display obvious methodical defects, so that they are unable to prove an effect of 'Ukrain'." (Finding by the Administrative Court, p. 10).

In reality, the criticism of these studies does not stand up to closer analysis. The authors of the study Gansauge et al., 2002 (Exhibit 7) are accused of treating the patients in the three study groups for different lengths of time. It is generally known, however, that therapy can consist of multiple cycles and that the differences in duration of therapy are due quite simply to the fact that the patients in the therapy groups Ukrain monotherapy and Ukrain/gemcitabine lived significantly longer than the patients in the group gemcitabine monotherapy. If you read the submitted documentation carefully, it soon becomes clear that all these allegations on the part of the experts have little to do with matters of fact. This raises the question of whether the above experts actually read the submitted documentation on Ukrain at all. Did they really fulfil their duty as independent experts, or did they neglect this duty and exceed their competences? One of the experts, Dr. J.-L. Robert, himself admitted that he had not read all the documentation. The authorising regulatory authority and the Administrative Court should recognise and remedy these deficiencies on the part of the experts. However, nothing of the sort has happened. Therefore my subjective public rights have been violated.

The Federal Ministry of Transport, Innovation and Technology was aware of the importance of my work, and was forced to note: "It is therefore incomprehensible on the other hand, why the Austrian health authorities are still sabotaging the authorisation efforts by Dr. Nowicky" (Exhibit 56).

Violation of the Right to a Fair Procedure as set out in Art. 6, Convention on Human Rights

I. Admissibility of the Complaint:

The appealed decision by the Federal Ministry of Social Security and Generations of 25 April 2002, no. 921.726/13-VI/16/02, violates my subjective public rights. With the finding now issued by the Administrative Court, all stages of appeal have been exhausted in Austria, so that I am legitimised to file a complaint with the European Court of Human Rights.

II. Facts:

With the appealed decision by the Federal Ministry of Social Security and Generations of 25 April 2002, no. 921.726/13-VI/16/02, my application for authorisation of the medicinal product "Ukrain" was rejected as set out in § 13 of the Austrian Drugs Act, Federal Law Gazette 185/1993 as amended in Federal Law Gazette No. 107/1994.

Ukrain is produced from *Chelidonium majus L.*, a wild plant that grows without cultivation in the northern hemisphere. This plant, commonly known as greater celandine, has been used as a natural remedy for more than 3500 years.

In addition to some poisonous substances, celandine also contains a single active substance that has to be isolated and converted in a complex chemical process in order for it to be used as a drug – namely in the form of intravenous or intramuscular injections. Ukrain has so far been researched in various countries on all continents and – although not authorised as a medicinal product in all countries yet – it has also been administered therapeutically to humans in many emergencies. All known drugs used in medicinal cancer therapy to date have a number of unpleasant side effects, because they generally have a toxic effect on the entire organism. By contrast, Ukrain is the first "malignotoxic" drug. I.e. it only kills off cancer cells and does not modify normal cells in any way, even at concentrations that are a hundred times higher than the concentration that kills off all cancer cells, as has repeatedly been shown by *in vitro* studies. Ukrain distinguishes between cancer cells and healthy cells. After administration Ukrain accumulates in the malignant tissue within minutes, as can easily be observed due to the auto-fluorescence of the substance. A phenomenon that may well open up entirely new aspects in cancer therapy, because Ukrain attacks only cancer cells and does not harm healthy cells. When administered to patients it does not cause any hair loss, nor any damage to either the haematopoeietic system or the liver or kidney. With a confirmed knowledge of these properties, I applied for authorisation of the drug Ukrain.

Since the drug Ukrain is absolutely non-toxic at therapeutic doses and does not have any damaging side effects whatsoever, and since its effectiveness had been demonstrated *in vitro* and *in vivo*, I could expect that my drug would be authorised quite soon.

As set out in the Austrian Drugs Act (§ 21 Par. 1 (1)), the authority reviewed the submitted documentation for completeness and requested me to submit missing documentation. Subsequently the authority contracted experts to prepare expert reports.

I very soon discovered a conspicuous bias on the part of these experts. In his expert report dated 26 February 2001, for example, Univ. Prof. DDr. Winkler claims – inconsistently with the file – that there was no consistent data establishing a mechanism of action for "Ukrain" in humans. The expert further stated the following:

"Nothing is known about the pharmacokinetics in humans. And as long as no detection method is presented for the assumed complex, this is not to be expected. Interactions with the pharmacokinetics of other substances were not investigated. There is not a single study of the clinical effectiveness that would prove this within the meaning of a phase III pilot study." (Exhibit 28)

This statement by the expert was accepted by the authority, although it is inconsistent with the file in several respects. Moreover the expert has failed to appreciate his function entirely, he has quasi told the deciding authority what to do instead of studying the facts and presenting a verifiable expert report.

The expert demands clinical studies before a possible authorisation should even be taken into consideration. This is not the expert's responsibility. It is the responsibility of the deciding authority to determine which documentation has to be submitted.

I have continuously tried to satisfy the increasingly new demands by the authority by submitting scientific papers that encountered significant acceptance internationally. However, the experts did not respond to the submitted research papers from all over the world. They never substantiated their negative claims regarding the submitted documentation, thus avoiding a scientific discussion. The deciding authority failed to perform its function of leading the procedure, but merely forwarded the submitted documents to the experts and accepted their statements stereotypically and uncritically. Ultimately, such a multitude of scientific papers and documents was available to the authority that even a layman would have had to realise on viewing the documents that the requirements of the Austrian Drugs Act had long been fulfilled.

Since Ukrain is not the only drug, the authorisation of which has been applied for in Austria, it is possible to compare how other drugs belonging to this complex have been handled by the authority. The drug Taxol was authorised, although there are currently no studies comparing it with other cytostatics, as can be seen from the Summary of Product Characteristics for Taxol (Exhibit 58). Ukrain was not authorised, although such studies are available. According to the Summary of Product Characteristics for Taxol, there are no studies investigating the potential carcinogenic effect, either. Nonetheless the experts certified that the drug Taxol was safe within the meaning of the Austrian Drugs Act. It has been shown repeatedly that Ukrain is absolutely non-toxic at therapeutic doses, and that it has absolutely no side effects. Nonetheless the expert claims that safety of the drug has not been shown; this, although the Drugs Council expressly stated in its Final Report that tolerability of the substance Ukrain was obviously very good. The expert apparently refuses to acknowledge the findings of a large number of research studies. He also refuses to enter into a scientific discussion. Yet it would be the duty of the deciding authority to require this from the expert.

A main point of criticism mentioned in the negative decision with regard to the authorisation of Ukrain is the fact that the structural proof, i.e. the structural formula of the active substance in Ukrain is missing. In accordance with the Austrian Drugs Act, submission of the structural formula is not even required, however.

In this case the expert and the authority are demanding something that is not even required by the law. By comparison with the authorisation procedure for Ukrain, authorisation of the drug Iscador during the same period deserves mention. Iscador is also

of herbal origin, and the submission of a structural formula was not required for the authorisation of Iscador. Nor is this even required in order to fulfil the conditions required by the Austrian Drugs Act.

Since the lawmaker is under obligation to apply the same legal consequences to the same facts and circumstances, this was a violation of the principle of equality. With the acceptance of the clearly incorrect claims by the expert, which are inconsistent with the file, my right to a fair procedure was also violated. This is all the more true because in my submissions I pointed out that he did not possess the necessary special knowledge required for the commissioned expertise, since his own publications show that he was working in other areas of expertise. In my letter to the Federal Ministry dated 25 April 2001, I requested the appointment of a different expert. The authority ignored this request. (Exhibit 59)

My fears were confirmed, when Prof. Winkler wrote: *"In Part III it is not guaranteed whether the observed effects were due to the suspected complex or to free alkaloids or even free thiotepa."* (Exhibit 28). No oncologist would ever dare make such a statement. It is known that neither thiotepa nor alkaloids have been in use for cancer of the colon. Ukrain does, however, have an anti-tumour effect in colorectal carcinoma – as shown by randomised clinical studies and *in vitro* studies by the NCI (Exhibit 3, 5, 6).

The documentation submitted by me proves that these requirements are absolutely fulfilled by the drug Ukrain within the meaning of the definitions in the Austrian Drugs Act.

I have submitted comprehensive documentation that irrefutably proves the effectiveness of Ukrain. It is now the turn of the authority and its experts to prove if anything is wrong with these research papers, or why the authority still assumes that Ukrain is not effective despite the documentation submitted. It cannot be, and it is also a breach of the General Administration Act, that the authority plays deaf without justification with regard to the submitted evidence. This is not only a violation of the principle of fair procedure, but is a clear case of arbitrariness.

In scientific circles, it is not usual to criticise a paper unless you can also furnish the necessary proof to justify the criticism.

In conclusion it is noted with regard to the rationale for the decision that the missing documentation claimed therein is certainly available in reviewable form, as any unbiased scientist can easily see.

The anti-cancer agent Ukrain is a drug, i.e. a substance or preparation of substances intended, in terms of the type and form of its placement on the market, to heal, alleviate or diagnose disease (namely cancer) when applied in humans (§ 1 Par. 5 (1), Austrian Drugs Act). At the same time, however, Ukrain is also a medicinal product because it is a drug which *a priori* is always produced with the same composition and is to be placed on the market under the same name in a form intended for dispensation to the consumer or user (§ 1, Par. 5, Austrian Drugs Act). Therefore the drug Ukrain, which is produced in Austria, can only be dispensed in Austria in accordance with the Austrian Drugs Act after it has been authorised. Therefore I submitted an application for authorisation of Ukrain to the Federal Ministry of Health and Environmental Protection on 28 June 1976. In a letter dated 23 June 1993, the Federal Ministry expressly informed me that there were no

formal objections to my application for authorisation (Exhibit 25). I submitted all the necessary documentation to the Federal Ministry as required by the Austrian Drugs Act for an application for authorisation (see § 15, Austrian Drugs Act). The submitted documents provide the scientifically unambiguous proof of the quality, effectiveness and safety of Ukrain as required by the provisions of the Austrian Drugs Act.

Based on the submitted evidence, it is ensured that in accordance with the state of the art and based on practical experience Ukrain, when used as intended, has no harmful effects on the human body in excess of the acceptable level in accordance with the state of the art of medicine, and that Ukrain contains substances or preparations, the safety of which appears to be confirmed by scientific findings and practical experience, and that the effectiveness of Ukrain has been sufficiently documented.

Thereby it must be emphasised that Ukrain has absolutely no harmful side effects when used as intended. The Final Report by the Drugs Council also expressly notes "that the tolerability of the substance is obviously very good" (Exhibit 25). Harmful effects of noteworthy significance have never occurred in the use of Ukrain, nor are any such effects claimed by the Federal Ministry. This good tolerability and absence of harmful side effects is a special characteristic of Ukrain.

Ukrain therefore offers a therapy for all those cancer patients in whom aggressive chemotherapy and/or radiation therapy is contraindicated.

The unlawful, if not to say planned obstruction of authorisation of Ukrain is also documented by the following incidents during the authorisation procedure.

In its decree no. II/520.382/1-9b-86 of 25 July 1986, the Federal Ministry claimed that not a single report on the effectiveness of Ukrain had been published in the internationally recognised literature (Exhibit 60). This claim is refuted by the documentation on file, however. To aggravate matters, the Federal Ministry prohibited the use of Ukrain in this decree on the grounds that allegedly no proof of effectiveness had been furnished, and that the Federal Ministry could not perform a cost-benefit analysis because of the missing documentation.

In accordance with the laws in effect at that time, such a ban would have had to be declared in an official decision, however, which was not the case. In further decrees in the year 1994 (Exhibit 61), namely before the amendment 1994/107 came into force (e.g. in a circular dated 25 February 1994, no. 21.405/1117-II/A/8/93), and based on its decree dated 25 July 1986, the Federal Ministry also pointed out this ban to various agencies. Thereby the Federal Ministry was not acting within the scope of the law either.

Such decrees are unlawful measures with which the Federal Ministry is attempting to deter physicians from doing their duty to help. One of many examples can be found in the book "Krebsmittel Ukrain, Kriminalgeschichte einer Verhinderung" (*"Cancer Agent Ukrain – The Crime Story of an Obstruction"*) by E. Thun-Hohenstein. The foreword tells the sad story of Stefan D. The 3-year-old child was paralysed, it could not speak or walk, and was sent home as therapy-refractory. The subsequent treatment with Ukrain produced a sensational result: His condition improved to such a degree that Stefan was able to both run and speak again. In a check-up examination, both the physicians and the parents were forced to abandon the therapy with Ukrain. The tumour started to grow again. As a result of this tumour growth, the boy was paralysed. The parents then decided

to ignore the ban on Ukrain therapy and started to treat the child with Ukrain themselves. Stefan is still alive, but unfortunately he is paralysed. (Exhibit 62)

The enclosed correspondence between Dr. Wojtowicz and the Federal Ministry shows that the authority is still trying to force doctors to abandon their duty of providing medical help. (Exhibit 63).

Although, if the decree by the Federal Ministry dated 25 February 1995, which does not have the character of a decision either, could be interpreted as a ban, measures (bans) can currently be implemented even without a preceding procedure in the exercise of direct power of command and coercion by the administrative authority in accordance with § 72 Par. 2, Austrian Drugs Act, the authority must in such a case issue an according written decision within 2 weeks, failing which the measure is deemed as cancelled. Assuming that such a ban had been issued on 25 February 1994, then this ban would have been cancelled again because it was not followed by a decision. In this case the Federal Ministry would therefore have had to repeal its alleged ban, which was not the case and which I am demanding now. In this context I would also like to make reference to § 12, Par. 1 (1) and (2) of the Austrian Drugs Act, according to which medicinal products do not require authorisation, if

a) they are intended for the implementation of clinical or non-clinical trials, or

b) a physician or veterinary doctor licensed to practice in Austria certifies that the medicinal product is urgently required in order to avert a life-threatening situation or serious health impairment and that in accordance with the state of the art such a result would not be possible with an authorised and available medicinal product. (Exhibit 64)

In the light of this provision, it is therefore necessary to review whether the Federal Ministry was authorised to issue such a warning in the first place. After all, the effect of the same is primarily to prevent the dispensation of Ukrain in the cases set out in Par. 1 (2) of § 12. However, this would also prevent administration of the drug Ukrain, which is absolutely harmless and free from side effects, in emergencies, i.e. it would refuse this drug for patients who depend on this drug when all other available therapies (chemotherapy and/or radiation) are contraindicated. It would further mean that the health insurance agencies, which had paid for the treatment with Ukrain up to this point, thereafter refused payment of the therapy with reference to the decree by the Ministry.

Based on the available documentation, however, Ukrain fulfils all the statutory requirements defined for dispensation of a drug for the above-named purposes. The ban on placing drugs on the market for which in accordance with the state of the art and practical experience it would not appear guaranteed that they do not have any harmful effects in excess of the acceptable level in accordance with the state of the medical science when used as intended, as set out in § 3, Austrian Drugs Act, does not apply here. The Final Report by the Drugs Council dated 3 November 1992 expressly states (as is also confirmed by others) that the tolerability of the substance is obviously very good. Harmful effects of any significance have never occurred with the use of Ukrain, nor does the Federal Ministry claim any such harmful effects; in its decree dated 25 July 1986 the Ministry merely regrets that the anti-cancer effectiveness of Ukrain is by no means documented and states – inconsistently with the file, by the way – that “according to our

knowledge" not a single proof of the effectiveness of Ukrain has been published in the internationally recognised literature.

The procedure by the Ministry is unlawful, the claims made in the decree are inconsistent with the file, and the entire process is directed against the principles of fair procedure. All the evidence required for the quality, effectiveness and safety of Ukrain as set out in the provisions of the Austrian Drugs Act is at the Ministry's disposal. There are also clinical studies available, including studies conducted in accordance with a study protocol approved by the Ministry.

The Federal Ministry and its experts obviously do not want to accept that the documentation in question, which provides testimony of the numerous successes in the fight against cancer achieved or described by researchers, is a part of and therefore reflects the state of the art. The Federal Ministry thereby relies on the expert report without further examination, ignores all other results of the procedure, and fails to acknowledge the evidence presented by me.

The demand for a placebo-controlled trial and simultaneous demand that *"no woman may be denied the current standard therapy"* is particularly noteworthy (Exhibit 39). This is a contradiction in itself! A placebo-controlled trial could only be conducted if a control group of patients remained without treatment, i.e. if treatment were only pretended. Quite apart from the fact that no doctor could be expected to proceed in this manner in the case of a disease as serious as cancer, because he would be subject to prosecution if he did, it is also extremely unethical to expect such a thing from the patients. The "Declaration of Helsinki" by the World Medical Association declares: *"Every patient - including those of a control group, if any - should be assured of the best proven diagnostic and therapeutic method"*, and then: *"...which holds that use of a placebo control in a clinical trial is unethical, if a proven therapy already exists. As a result, patients may suffer unnecessarily and many even risk death"*.

The above shows that *de facto* this clinical trial is being prevented by making contradictory demands that cannot be fulfilled. This also violates the principle of equality and the right to a fair procedure.

The following complaints follow from all that has been said before:

1. The constitutionally guaranteed principle of equality has been violated, because the same legal consequences are not applied to the same facts and circumstances.

2. The right to a fair procedure guaranteed by the Constitution and by the Convention of Human Rights has been violated, because the Ministry failed to fulfil its function as procedural moderator, based its decision uncritically on incorrect expert reports, and failed to replace the obviously biased expert despite being informed and requested to do so by the applicant.

3. The decree dated 25 July 1986, no. II/520.382/1-9b/86 and the circular dated 25 February 1994, no. 21.405/1117-II/A/8/93, based on the decree dated 25 July 1986, in which the drug Ukrain was banned, is regarded as the unlawful exercise of a direct power

of command and coercion on the part of the administrative authority.

4. Substantiation:

a) Based on the principle of equality, the lawmaker and therefore the administration is obliged to apply the same legal consequences to the same facts and circumstances. Differing regulations, including a legal act by the administrative authorities, which are not based upon corresponding factual differences, represent a breach of equality. For authorisation as set out in the Austrian Drugs Act, proof of safety of the drug must be provided among other things. As set out in § 3, placing drugs on the market for which in accordance with the state of the art and practical experience it would not appear guaranteed that they do not have any harmful effects in excess of the acceptable level in accordance with the state of the medical science when used as intended, is not permitted.

Many scientific papers as well as numerous case reports have shown that the medicinal product Ukrain does not have any harmful side effects whatsoever. Even the Final Report by the Drugs Council confirms that Ukrain is well tolerated. Comparative studies with other cytostatics are also available for Ukrain. The same applies to the proof that Ukrain does not have any carcinogenic effects. Nonetheless authorisation of Ukrain was denied on the grounds that its safety was not established. By contrast, the Summary of Product Characteristics for the drug "Taxol" states: *"There are no investigations of the potential carcinogenic effect of Taxol."* Further: *"With regard to combination with other anti-tumour agents, in vivo studies with mice confirm the synergy effect of Taxol and Cisplatin. Clinical studies with this and other cytostatics are not available to date. Comparative studies with other cytostatics are not available to date either"*. (Exhibit 49) The Summary of Product Characteristics also lists serious side effects. It is proven that the drug Ukrain, by contrast, does not have any harmful side effects whatsoever.

It is obvious that in this case entirely different legal consequences were applied to fulfilment of the safety documentation requirements set out in the Austrian Drugs Act in cases of at least equivalent evidence being available. According to the decree by the Federal Ministry dated 25 April 2002 a main point of criticism is the fact that the structural proof for the active substance Ukrain is missing. The fact that the negative decision is substantiated by the missing structural proof is seen as a violation of the principle of equality, especially since a structural proof was never submitted or even requested for the drug Iscador. This drug has long been authorised, however. Like Ukrain, Iscador is of herbal origin. In drugs of herbal origin it is naturally much more difficult to furnish proof of the structure than in the case of synthetic products. In many cases it is not even possible to furnish such a proof of the structure with the scientific methods currently available and at a reasonable economic cost. Therefore the Austrian Drugs Act basically does not demand such a proof of structure.

The fact that the drugs Taxol and Iscador were authorised, even though Taxol is a highly problematic substance in view of its safety and proof of the structure was never demanded or furnished for Iscador, is seen as a violation of the principle of equality, since authorisation of the drug Ukrain was denied although proof that it does not have any harmful side effects was furnished, and a proof of the structure was submitted, even if this proof of the structure gives rise to scientific discussions.

Since not only legislation but also its enforcement is bound by the principle of equality, this means that the valid legal regulations must be applied equally to all citizens. With the appealed decision by the Federal Ministry, the legislation of the Austrian Drugs Act was applied to me in breach of equality with reference to my application for authorisation of the drug Ukrain inasmuch as I was required to provide evidence which, as already shown, was not required for the drugs Taxol and Iscador, even though these drugs are also cancer therapy agents. With this procedure, the Federal Ministry acted arbitrarily, which also represents a breach of the principle of equality in enforcement. This is also substantiated by the fact that the deciding authority failed to investigate the decisive issues, because it stereotypically accepted the experts' opinions and allowed the documents and papers prepared by renowned researchers and submitted by the applicant to be ignored.

In its decision, the deciding authority – without critical inspection of the expert report and without consideration of my documentation – simply accepts the claims by the experts, even if, as is almost always the case, they lack every justification. Consequently, the decision also lacks any real substantiation. This is also seen as a violation of the principle of equality. It is further seen as a violation of the right to a lawful judge, because in reality the authority did not decide on the basis of a critical assessment, but rather based its decision on an expert report without review.

5. Violation of the Right to a Fair Procedure as set out in Art. 6, Convention on Human Rights

a. In connection with the expert:

The legal framework for the work of the expert does not represent any uniform field of law. It originates from various fields of law, especially the codes of civil and criminal procedure, administrative procedure law, the civil code and material criminal law; thereby aspects of constitutional law must also be observed.

The term expert is associated first and foremost with a person who must provide an expert report within the framework of a court or administrative authority procedure to support the court or administrative authority in resolving an issue of crucial importance for its decision. This role of the expert is undoubtedly very important, and it is also the role to which the greatest attention is paid in teaching and judicature.

Those cases in which the expert acts at the request of or on behalf of the state must be distinguished from the expert's activities on the private sector. In the case on hand, we are dealing with experts in the classical function of the expert in an administrative procedure, i.e. as an expert provided to the authority responsible for a procedure within the state administration apparatus by another agency.

The findings by the expert must be evaluated by the authority. It is not admissible that the authority simply accepts an expert report or its contents blindly without further review. It must definitely verify that the essential requirements for an expert report have been met, e.g. whether the facts have been ascertained correctly and whether the conclusions drawn in the expert report are clear, cogent, and understandable and verifiable for everyone. This means that the authority also has to verify whether the expert has underpinned his

statements with clear evidence, and whether he has dealt with the applicant's presentation in a materially objective and scientifically adequate manner.

Thereby the role of the constitutionally protected right is to guarantee that the roles are reasonably divided between the expert and the administrative authority. Based on the dichotomy of factual and legal issues, the expert is assigned the task of preparing an expert report on the facts, and the authority is responsible for legal subsumption and decision-making. If the authorisation of a drug is to guarantee that no risks to health or life will be caused when used as intended, it is the task of the legal interpretation *inter alia* to determine the meaning of the hazard concept, and thereby to assess how great the allowed residual risk may be. This is clearly a legal issue and must be decided by the authority. The determination and prognosis of the anticipated negative effects of the drug, on the other hand, are factual issues that must be answered as such in the expert report by an expert.

The required division of roles between the expert and the authority is called into question in many respects in this procedure *in praxi*, however. As a result of the deficient procedural management by the authority, the maxim of clarity and understandability of expert reports for the parties and for the authority becomes a fiction. Yet, if the authority is not in a position to understand and comprehend the expert report, then it does not have any possibility to assess its value as evidence, either. In this case, its discretionary evaluation of evidence is therefore reduced to zero. As a result, the authority is therefore at the mercy of the expert's opinion, which it cannot verify, in an issue crucial to the decision, and the expert's report becomes the authority's decision.

Since the expert proves to be clearly biased in this context with his statement: *"…From my point of view I can only recommend denial of the authorisation based on the submitted chemical-pharmaceutical documentation"* (Expert Report Dr. J.-L. Robert, Exhibit 28), a fair procedure can no longer be guaranteed at this point.

In this context attention must be drawn to the special guarantee functions, which the law must assume whenever the expert is acting within the sphere of the state and his expert report is contributing towards a decision by the authority. The more dependent such a decision is on the result of an expert report, the more the code of law must provide for the safeguarding of objectiveness and verifiability of the relevant expert report. This postulate goes beyond the framework of a policy-of-law requirement. It is at the same time a maxim derivable from the general call for objectivity in the principle of equality, and as such has constitutional law relevance. In this context attention must once more be drawn to the supervisory and moderating function based on the official appointment, which the authority must fulfil accordingly to the benefit of the procedure and in the interest of the parties in the fulfilment of its attendant obligations.

Art. 6 of the Convention on Human Rights establishes a number of constitutional standards to guarantee a fair procedure in civil and criminal law cases. In such matters everyone has a right to decision on his case by an independent and unbiased authority, a so-called tribunal. The importance of Art. 6 of the Convention on Human Rights, especially for legal protection in the area of administration, only became clear gradually in the course of the development of judicature.

It is inconsistent with the guarantees of a fair procedure, if a decision is based on the expert report by an expert who should not even be acting as an expert in the procedure on hand and who moreover proves to be clearly biased. The fact that I requested the appointment of another expert, which request was ignored by the authority, is a further aggravation.

At this point, attention is also once more drawn to the general import of the issue of authorisation of the drug Ukrain, since the deciding authority must certainly have been aware thereof. There are a great number of cancer patients for whom the current standard therapies are unsuitable because of the great number of harmful side effects of these therapies, quite apart from the often very limited effectiveness of these therapies. Because of its good tolerability and the fact that it has absolutely no harmful side effects but a therapeutically good effectiveness, Ukrain is the drug that all these patients depend on urgently. However, despite submission of all the evidence required by the Austrian Drugs Act, authorisation of the drug Ukrain has been denied as the result of an unfair procedure.

In the opinion of the ECHR, an assessment of the fairness of a procedure also depends significantly on the superficies. This superficies is no longer intact, if there are any "doubts about the neutrality of an expert whose expert report is significant for the decision by the authority".

However, an extension of the requirement of independence and neutrality of the decision-making authority to its experts must at the same time be seen in the light of the principle of visible justice. Thereby it is not enough if the relevant expert really were to be independent and neutral; it must much rather also be legally guaranteed that anything that could cause the parties to have objectively justified doubts about the independence and neutrality of the expert on the face of things must be avoided.

The guarantee of objectiveness and verifiability of the expert report requires that the authority defines adequately precise and technically adequate requirements with regard to the qualifications of the expert and the preparation of his expert report. This applies in particular when strong group interests are at stake.

Last but not least, guaranteeing the objectiveness and verifiability of expert reports also includes the possibility of an effective legal protection of the party concerned from the expert and the result of his work. In the case on hand, this protection is only possible in the form of a complaint to the ECHR.

As shown by the explanations in the appealed decision, the Federal Ministry notified all agencies of the provincial governments in a circular dated 25 July 1986 that effectiveness the medicinal product Ukrain, which was not authorised but was already being used by various doctors in cancer therapy, was not adequately established and that placing on the market of such an untried agent was forbidden in accordance with the provisions of the Austrian Drugs Act. The addressees of the circular were instructed to prohibit the distribution of Ukrain and its uncontrolled use. The Medical Council and the Chamber of Pharmacists were informed in the same manner.

This circular is based on the decree by the Federal Ministry dated 25 July 1986, no. II/520.382/1-9b/86. This decree is unlawful, its substantiation is inconsistent with the file, and it is based on false facts and claims. This will be dealt with in more detail below. It is noted at this point that as a result of this procedure by the Ministry, which – as I have

already said – was unlawful, I was seriously obstructed in the pending authorisation procedure for the drug Ukrain at that time. It is clear that the claim widely spread by the Ministry that the use of Ukrain was prohibited in accordance with the Austrian Drugs Act seriously obstructed the acquisition of case experiences with Ukain for two reasons: On the one hand the practising physicians, who naturally do not have an extensive legal education, were intimidated and on the other hand this was an understandable occasion for the health insurance agencies to refuse to reimburse the costs – even for successful treatment with Ukrain. As shown by the decision, this prohibition decree is causally linked to the authorisation procedure and is an integral part of the same, so to speak. This fact is seen as an impairment of the right to a fair procedure; it moreover resulted in the suppression of case reports and also put me under strong material pressure.

6. Unlawfulness of the exercise of direct powers of command and coercion by the administrative authority

In its decree dated 28 July 1986, no. II/520.382/1-9b/86, the Federal Ministry of Health and Consumer Protection claims that it banned the use of Ukrain on the grounds that no proof of its effectiveness had been furnished. Even in accordance with the laws in force at that time, such a ban should have been issued in the form of a decision, which was obviously not the case however. In further decrees in the year 1984, namely before the amendment 1994/107 came into force (e.g. in a circular dated 25 February 1994, no. 21.405/1117-II/A/8/93), and based on its decree dated 25 July 1986, the Federal Ministry also pointed out this ban to various agencies. Thereby the Federal Ministry was not acting within the scope of the law either.

If the decree by the Federal Ministry dated 25.2.1994, which does not have the character of a decision either, could be interpreted as a ban, measures (bans) can currently be implemented even without a preceding procedure in the exercise of direct power of command and coercion by the administrative authority in accordance with § 72 Par. 2, Austrian Drugs Act, the authority must in such a case issue an according written decision within two weeks, failing which the measure is deemed as cancelled.

Assuming that such a ban had been issued on 25 February 1994, then this ban would have been cancelled again because it was not followed by a decision. In this case the Federal Ministry would therefore have had to repeal its “alleged” ban, which was not the case despite a request to do so, and which I am demanding now.

According to its decree dated 25 February 1994, the Federal Ministry banned the dispensation of Ukrain in accordance with § 12 Par. 1, II Austrian Drugs Act. Thereby the authority was not acting within the scope of the law. In its explanations, it made the concept “success” used therein dependent on “state of the art”. § 12 Par. 1, 2, Austrian Drugs Act, however, speaks of averting a life-threatening situation or serious damage to health, and basically limits the use of an unauthorised medicinal product only to the extent that an unauthorised and available medicinal product is available to avert the indicated risk or damage.

The provision in § 3, Austrian Drugs Act, prohibits the placing on the market of a drug that in accordance with the state of the art and practical experience could result in harmful effects for humans in excess of the level acceptable in accordance with the state

of medical science if placed on the market. However, the reports submitted to the Ministry clearly exclude any such hazards. The Federal Ministry obviously does not want to accept that the submitted documentation, which provides testimony of the numerous successes in the fight against cancer achieved or described by researchers, is a part of and therefore reflects the state of the art. Therefore placing Ukrain on the market is admissible within the scope of § 12 Par. 12, 2 Austrian Drugs Act. The behaviour by the Federal Ministry is therefore not within the scope of the law.

In accordance with the above presentations, the Federal Ministry is opposed exclusively to the use of the drug Ukrain in accordance with § 12 Par. 1, 2. It does so with an incorrect and moreover changing substantiation.

In its decree dated 25 July 1986, the Ministry claims that no proof of an appropriate effectiveness of Ukrain had ever been published in the internationally acknowledged literature. This claim is obviously false. Reference is made to the documentation available to the Ministry and enclosed with the file. This documentation contains repeated proof of the successful aversion of a life-threatening situation or serious damage to health. Even the Final Report by the Drugs Council of 3 November 1992 (Exhibit 25), which is cited by the Federal Ministry, speaks of "clinical reports of patients who showed the following responses:

a. tumour growth standstill without further metastasing

b. partial remissions

c. total remissions, including cases that had already lasted for several years (up to 10)."

As the documentation shows, a large number of patients in several countries worldwide have already been treated successfully with Ukrain.

The Federal Ministry further objects that in the case of Ukrain it did not seem confirmed in accordance with the state of the art and based on practical experience that no harmful side effects in excess of the level acceptable in accordance with the state of the medical science would occur with Ukrain when used as intended. This ascertainment is inconsistent with the file, since the available documentation shows that the administration of Ukrain does not cause any damage to human health, as was also expressly noted by the Drugs Council in its Final Report. So far not a single case is known in which any harmful effects occurred.

If you read the expert reports, and the decision by the Federal Ministry and the Finding by the Administrative Court based on these expert reports, you could have the impression that I did not submit any significant documentation at all. Thereby it is clear from a simple perusal of the documents, even for the layman, that the application was well founded. Instead of fulfilling their duty and assessing the submitted documentation objectively, the experts merely sought every reason to reject the application and suggested this clearly negative position to the authority. This raises the suspicion that the experts were specifically chosen so that they would find an excuse for a negative assessment of the application. Prof. Winkler took the liberty of making judgements that were not within his field of expertise. This resulted e.g. in the following unqualified statement: *"It is unclear…whether observed effects...due to free alkaloids or even free thiotepa."* Yet no oncologist would ever dare make such a claim, since it has long been

known that neither thiotepa nor celandine alkaloids were used clinically for colorectal carcinoma. With his claim *"…chemical-pharmaceutical quality of the active substance cannot be assessed on the basis of the submitted data, because its structure is unknown…"* (AdmC Finding, p. 18, 1st paragraph, Exhibit 1), Dr. Robert also makes it clear that he is not very familiar with "herbal preparations". He claims (AdmC Finding, p. 4): *"Accordingly, inconsistent analysis results would also be obtained in the identity, content and purity tests for the active substance and from batch to batch of the finished product. There was not sufficient data available with regard to the composition, active substance declaration, quality of the components and shelf life"*. What proof does the expert have for these allegations? The claim is moreover inconsistent with the file, because a GLP-compliant 4-year stability study was conducted by the independent company SGS Lab Simon (Belgium) and submitted (Exhibit 65). Page 17 of the Finding states: "He thereby submitted a statement by Dr. Tittel dated 31 March 2002, according to which it should be attempted to characterise the chemical composition of the mixture to the extent that a reproducible product of equal pharmacological effectiveness could be obtained from batch to batch. Experimental proof of this inter-batch reproducibility had been furnished repeatedly. The arguments by the expert Dr. Robert were thus shown to be untenable." From this confrontation of two opinion, the court must surely have recognised that the appointment of another expert was unavoidable.

For all the above-named reasons it is clear that I could never have expected a fair procedure before the authorisation authority.

In conclusion I would like once more to emphasise that in my case Art. 6 of the Convention on Human Rights has been violated -

- by the Austrian Ministries issuing unlawful decrees
- by the Austrian courts making claims inconsistent with the file
- by the documents submitted later not being read by the appointed experts, although they then prepared expert reports inconsistent with the file
- by my rejection of an expert not being taken into consideration
- by the court issuing a judgment on the basis of unread documentation and a rejected expert's report
- by not presenting the expert reports to me in time for me to be able to respond to them, which would have rendered the issue of a negative decision impossible
- by the Administrative Court not dealing with all the points of the complaint in its last finding
- by delaying the final decision after submission on my part of all the required documents, by applying meanwhile amended laws, although my application has to be processed on the basis of the legislation in force in 1976
- by the court not taking into consideration e.g. the statement by Prof. Dr. Hitzenberger (member of the Austrian Drugs Council) in Expert Report No. 558, page 10, last paragraph (Exhibit 10), that *"a clinical could also be approved in Austria under circumstances, because the substance is obviously very well tolerated"*, and even Prof. Hitzenberger expresses astonishment that Ukrain has not already been authorised (page 1, 3rd paragraph): *"Based on the type and scope of documentation it is clear that we are dealing with a very well developed preparation…"* and further on page 9, last paragraph: *"both in terms of*

pharmaceutical technology and in terms of clinical pharmacology the question is why Ukrain was submitted to the Drugs Council at all." (Exhibit 25).

Based on the above presentations I am of the opinion that in connection with the procedure leading to the appealed decision my right to a fair procedure was violated, that I was *de facto* deprived of the statutory judge, and moreover direct power of command and coercion was unlawfully exercised by the administrative authority by prohibiting the use of Ukrain in accordance with § 12 Par. 1, 2, Austrian Drugs Act, in contravention of this same Act.

For the above reasons and within the set deadline I am herewith submitting to the European Court of Human Rights the

Petition:

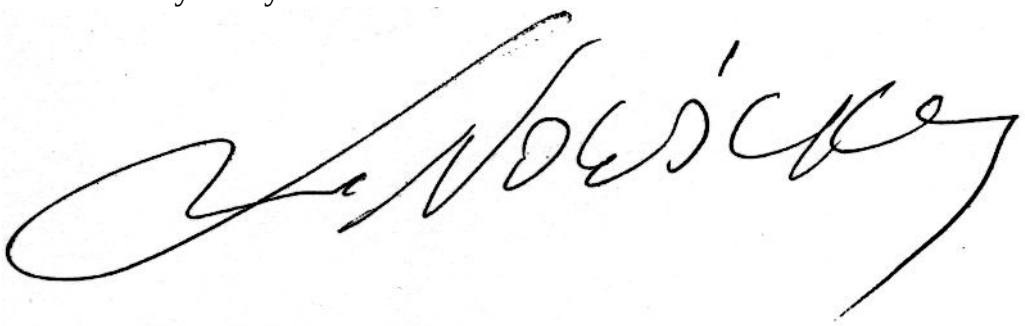
1. to declare the complaint admissible, subsequently
2. to ascertain that the applicant's right to a due and proper procedure as set out in Art. 6 Par. 1 of the European Convention on Human Rights has been violated by the Republic of Austria, and
3. to order the Republic of Austria to indemnify the applicant for the damages and costs of this procedure and the national procedure, as well as the damages suffered by the applicant as a result of the non-compliant implementation of the authorisation procedure.

I submit the following documents:

1. Finding no. 2002/10/0096-8) by the Administrative Court
2. Legal Expertise Walter
3. Results from NCI (Bethesda, Maryland, USA)
4. Sotomayor et al.(1992)
5. Susak et al, 1996
6. Bondar et al, 1998.
7. Gansauge et al, 2002
8. Gansauge, 2003: Final Evaluation, Ulm Study
9. 13th World Congress of Chemotherapy, 1983
10. Wodniansky
11. Univ. of Münster, Investigation of Cytotoxicity
12. Seibersdorf 1998
13. Seibersdorf December 2001
14. Seibersdorf January 1999
15. Seibersdorf November 1999

16. Seibersdorf November 1999
17. Seibersdorf May 2000
18. Seibersdorf October
19. Documentation of registrations
20. Decision by the Federal Ministry of Health, Sports and Consumer Protection of 2 June 1995
21. Finding by the Administrative Court of 15.4.1996
22. Letter Pfleger dated 8.1.1998 to Federal Ministry of Labour, Health and Social Affairs
23. Letter Nowicy Pharma dated 9.4.1998 to Min.Rat Michtner
24. Decision by the ECHR dated 24.2.2005
25. Letter from the Federal Ministry of Health, Sports and Consumer Protection dated 23 June 1993 (Arrouas)
26. Reports by doctors and researchers on experience with Ukrain
27. Expert Report Robert
28. Expert Report Winkler
29. Ernst/Schmidt BMC Cancer
30. Summary of Product Characteristics Mabthera
31. Summary of Product Characteristics Gemzar
32. Chlopkiewicz et al, 1992
33. Juszkiewicz et al, 1992
34. Beger et al. Statement on Expert Report by Professor Dr. Winkler
35. Waknine, FDA Approvals Clobex and Tarceva
36. Placebo Problem
37. Letter Reinthaler dated 8.5.1995
38. Ars Medici
39. Pittner, fax dated 17.7.1995
40. Disciplinary action (summons) against Dr. G. Nowicki
41. Liepins et al 1992
42. 17th Internat. Cancer Congress
43. Roublevskaja et al, 2000, Epidermoid Cancer
44. Fomin et al, 1996
45. Roublevskaja et al, 2000, Prostate Cancer
46. Roublevskaja et al, 2000, Keratinocyte cells
47. Doroshenko et al, 2000, Fluorescence
48. Pharmacokinetics 2001
49. Susak et al, 1996
50. Doroshenko et al, 2000, Blood Plasma
51. Kleinrok et al, 1992
52. Jagiello-Wojtowicz et al, 1996, Antinociceptive effect
53. Jagiello-Wojtowicz et al, 1996, Interaction
54. Nahler, Expert Report 2002
55. Letter from Federal Ministry of Health and Women’s Issues dated 3.9.2004
56. Letter from Federal Ministry of Transport, Infrastructure and Technology (Rozsenich) dated 21.8.2000
57. Alkaloid Content in 15 Batches of Ukrain

58. Summary of Product Characteristics Taxol
59. Letter Nowicky Pharma 25.4.2001 (Non-acceptance of expert)
60. Letter from Federal Ministry of Health and Environment 25.7.1986
61. Letter from Federation of Austrian Social Insurance Agencies of 11.3.1994
62. Book “Krebsmittel Ukrain, Kriminalgeschichte einer Verhinderung” (*Cancer Agent Ukrain – Crime Story of an Obstruction*)
63. Case Dr. Ewa Wojtowicz
64. § 12, Austrian Drugs Act 1994
65. Stability Study



Dipl.-Ing. Dr. Wassil Nowicky Vienna, 2 March 2006