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

20.1.2006
Nr/Cs NOWI/03030

Applicant: Dipl.-Ing. DDr. Wassyl Nowicky
1040 Vienna, Margaretenstraße 7

represented by:
Power of attorney granted
(§ 8 Par. 1 RAO):
P130765

for: Article 6 of the European Convention on Human Rights

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

Duplicate
1 Power of Attorney
20 Exhibits

1. I have appointed the law firm Schönherr Rechtsanwälte GmbH as my representative. A power of attorney is enclosed as Exhibit ./1.

2. Facts of the Case

2.1 In my application dated 13 August 2002, I appealed to the European Court of Human Rights because in my opinion the duration of the authorisation procedure for the medicinal product developed by me, Ukrain, was unreasonable within the meaning of Article 6, European Convention of Human Rights. The procedure was pending for Application No. 34983/02. In the judgment dated 24 February 2005, the Republic of Austria was condemned on this count. To avoid repetitions, I refer to my pleas in the application dated 27 August 2002, my reply dated 27 February 2004, and the judgment dated 24 February 2005 in case 34983/02. I am raising the pleas made in that case and the facts ascertained in the judgment to my pleas in this procedure.

2.2 For the application in this case, the facts of the case require completion in as much as the Administrative Court denied my complaint of 7 June 2002 in its Finding dated 21 November 2005 (Exhibit ./2). Despite the complex facts of the case, the justification was very short. The considerations of the Administrative Court start on page 11 with a one-and-a-half page citation of statutory provisions. There is no detailed discussion of the points presented by me in my complaint dated 7 June 2002 (Exhibit ./3) and reply dated 12 December 2002 (Exhibit ./4). The Administrative Court confirms the negative decision by the Federal Ministry of Social Security and Generations of 25 April 2002 in principle with the argument that structural proof of the medicinal product Ukrain had not been provided. Thereby the Administrative Court relies less on the presentations in the appealed decision, but primarily on an expert opinion by the appointed expert Dr. Robert dated 28 December 2001 (Finding of 21 November 2005, page 17 f). This expert report by the expert Dr. Robert (Exhibit ./5) was not delivered to me during the proceedings with the authorising authority, as the Administrative Court also concedes in its Finding (p. 17). The same applies to an expert opinion by the expert Dr. Winkler (Exhibit ./6) significant for the denial of my application for authorisation, which was not even dealt with by the Administrative Court. Both documents were not delivered to me until delivery of the decision by the Federal Ministry of Social Security and Generations of 25 April 2002.

2.3 The facts of the case clearly indicate that the authority of jurisdiction for the authorisation of medicinal products, most recently the Federal Ministry of Health and Women's Issues, intentionally or unintentionally selected experts who did not have the necessary qualifications. The expert Dr. Winkler, quoted by the Administrative Court on page 6 of its Finding, cannot even say which substance – thiotepa or alkaloids – was responsible for the effect of Ukrain. Yet it is a fact that *in vivo*, *in vitro* and *clinical studies* show that neither thiotepa nor alkaloids are effective against cancer of the colon. By contrast, the medicinal product developed by me, Ukrain, has an anti-tumour effect in colorectal carcinoma (= cancer of the colon), as has been shown by randomised clinical studies as well as *in vitro* studies (Exhibit ./7).

The fact that the therapeutic index, i.e. the difference between effective and toxic dose, is only 1.2 – 1.8 for chemotherapeutic agents is ignored. This can have fatal consequences in the case of accidental overdosing. A double-blind study with placebo was not demanded for these preparations. Nonetheless they are the standard therapy for almost all forms of cancer. Ukrain on the other hand has a therapeutic index of 1250, therefore there is no risk of overdosing and its application is safe. Yet the performance of a placebo-controlled study

is demanded as a condition for its authorisation. The use of Ukrain will not even be permitted for therapy-refractory patients.

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. 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.".* Thereby the expert first ascertains that according to the data submitted Ukrain does not have any toxic effects. At the same time, the fact that authorisation of Ukrain has also been applied for therapy-refractory patients is ignored. Yet these are, as already presented in the first procedure, patients who have been abandoned by the orthodox school of medicine. For these patients, every day by which their life is prolonged is important, and the toxic sequelae of clinical long-term use cannot play a role. If such sequelae were to occur, the abandoned therapy-refractory patient would already have lived much longer than predicted by the orthodox school of medicine anyway. It should also be 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. For many of these preparations, toxicity studies are not even conducted. By way of example, I am submitting the Summaries of Product Characteristics for the well-known medicinal products Mabthera and Gemcitabine (Exhibits ./8, ./9).

2.4 The undisguised, in no way comprehensible criticism of the results of the Ulm Study by the expert Dr. Winkler also shows the manner of action in my authorisation procedure. This criticism is difficult to understand and was clearly refuted by the Ulm Group (Exhibit ./10). The authors were seriously accused of having treated the patients in the three studies for different lengths of time. That is almost cynical. The differences in duration of treatment result quite simply from the fact that the patients in therapy groups B (Ukrain monotherapy) and C (Ukrain plus Gemcitabine) lived significantly longer than the patients in group A (Gemcitabine monotherapy). The average survival in group A was five months, which corresponds with the results from other studies, whilst in the two other groups the average survival of 10 months was almost twice as long. In other words: **Only because the use of Ukrain proved to be more successful than a commercial product, the study was to be considered useless because of differences in the study duration.** With regard to the further demand by the expert Dr. Winkler to conduct a placebo-controlled double-blind study, I refer to my pleas in case 34983/02. It is truly cynical to expect therapy-refractory patients to participate in a study where they risk being assigned to the placebo group. For cancer patients this must be refused point blank.

2.5 As far as the structural proof is concerned, it serves exclusively to guarantee reproducibility of a medicinal product in all production batches. This reproducibility was demonstrated by me, but of course the Administrative Court does not even mention that. I am enclosing the statement by Dr. Tittel OHG dated 25 June 2001 on this count (Exhibit ./11). In this statement, the claims by the expert Dr. Robert are refuted, at least in as much as they were actually delivered to me and I had an opportunity to comment on them. The statements by Dr. Tittel OHG are unambiguous: The 2nd paragraph on page 3 literally states: *"The claim by Dr. Robert that synthesis cannot be performed under GMP conditions is purely and simply an allegation that is not proven. I can assure you that the synthesis method tested, reproduced and described by us can be reproduced in appropriate laboratories under GMP rules at any time."* Further: *"A release specification that includes all the analysis methods required in accordance with the latest state of the findings concerning the preparation for verification of the reproducible quality of the medicinal*

product is available! (page 3, 5th paragraph)" Due to lack of service in the authorisation procedure, I was unable to respond to Dr. Robert's rejoinder.

Quite generally Dr. Robert does not appear to have studied the documentation with the intensity to be expected from an expert. On page 6 of his statement dated 5 April 2001 (Exhibit ./21) in the 3rd conclusion he writes, for example:

"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 Quality Directives 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 (DC: coloured). 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.

3. Legal Argument – Violation of Article 6 Par. 1 of the European Convention on Human Rights

3.1 In accordance with Article 6 Par. 1 of the European Convention on Human Rights, everyone is entitled to a fair and public hearing within a reasonable time by an independent and impartial tribunal established by law in the determination of his civil rights and obligations or of any criminal charge against him. In its judgment dated 24 February 2005, the European Court of Human Rights has already established that my right to obtain authorisation of the medicinal product Ukrain is a civil right within the meaning of Article 6 Par. 1 of the Convention. Therefore reference may be made to this judgment.

3.2 In application 34983/02 I also relevated that my case had not been judged by an independent tribunal within the meaning of Article 6 Par. 1 of the Convention. In my opinion, the subsequent control by the Administrative Court is not sufficient in the case on hand. In its judgment dated 24 February 2005, the Court made reference to varying decisions with regard to this issue, but ultimately rejected the complaint because the authorisation procedure was still pending at the time (paragraphs 40 and 41 of the judgment).

3.3 The European Court of Human Rights has repeatedly decided that a tribunal within the meaning of Article 6 Par. 1 of the Convention must have full power of cognition with regard

to both technical and legal issues (judgment 22.10.1984 No. 5/1983/61/95 – *Sramek*; 24.11.1994, No. 35/1993/340/509 – *Beaumartin*). The Administrative Court does not have full power of cognition, at least in the case on hand a fair procedure was not possible due to the restricted competences of the Administrative Court. The Administrative Court's power of review is based on § 41 Par. 1 of the Administrative Court Act 1985. This provision sets out:

"In so far as the Administrative Court does not find any unlawfulness deriving from the respondent authority's lack of jurisdiction or from breaches of procedural rules (§ 42 Par. 2 (2) and (3)), and § 38 Par. 2 is not applicable, it must examine the impugned decision on the basis of the facts found by the respondent authority and with reference to the complaints put forward (§ 28 Par. 1 (4). If it considers that reasons which have not yet been notified to one of the parties might be decisive for ruling on one of these complaints, it must hear the parties on this point and adjourn the proceedings if necessary."

The cited passage from the law clearly shows that the Administrative Court must review the appealed decision based on the facts of the case rejected by the respondent authority. Thus it is clear that the Administrative Court must accept the facts ascertained by the authority and cannot ascertain the facts differently. In this case the respondent authority was the (former) Federal Ministry of Social Security and Generations as the first and only instance. As already set out in Par. 2 above, the negative decision by the respondent authority was taken in a rather dubious manner. In particular, I must repeat that two expert reports of significance for the decision were only delivered to me together with the decision. Although I commented on these in my complaint, the Administrative Court was unable to ascertain the facts differently due to the provisions of § 41 Par. 1, Administrative Court Act. A fair procedure by an independent tribunal was thus guaranteed.

The opinion presented here by me on the power of cognition of the Administrative Court was confirmed by the European Court of Human Rights in the *Gradinger* judgment (judgment of 23.10.1995, 33/1994/480/462). However, I am also aware of those decisions in which the Austrian Administrative Court was accorded the quality of a tribunal. Naturally the Court has always stated that this issue must be assessed based on the merits of the individual case. In my case in particular, an independent tribunal with full decision-making power, namely also with regard to the facts, would have been necessary to guarantee a fair procedure. It may be pointed out that the Administrative Court is decides as a senate of five members, all of them members of the legal professions, and therefore is not in a position to assess complex matters of fact by consulting own, independent expert. I further make reference to my plea in application 34983/02, namely that problems are caused for any person who has anything to do with Ukrain in Austria. This applies particularly to doctors who dispense Ukrain absolutely legally on the basis of § 12 Par. 1 (2), Austrian Drugs Act (legal text = Exhibit ./12). Disciplinary action was taken against the physician Dr. Grazny Nowicki (not related to me) because of the use of Ukrain (Exhibit ./13). The same goes for Dr. Adolf Langer (Exhibit ./14). Some physicians encountered difficulties caused indirectly by the fiscal authorities (Exhibit ./15). Other examples can be found in the refusal to sell alkaloids and thiotepa to my company, as well as obstructions to filling Ukrain into ampoules by several pharmaceutical companies.

All these incidents are due to the negative and biased opinion of the competent authority. As early as 1986, the then competent Federal Ministry of Health and Environmental Protection declared in a decree that the effectiveness of Ukrain was not proven. The subordinate authorities were ordered *"to suitably inform all other agencies involved about the case and to take the necessary measures to prevent the further distribution and further*

uncontrolled use of Ukrain in contravention of the applicable laws immediately (Exhibit ./16)*."* In 1994 the Federal Ministry of Health, Sports and Consumer Protection issued a further decree proclaiming that the use of Ukrain outside clinical trials was not permissible (Exhibit ./17). Decrees are not contestable legal acts, but rather designed as internal instructions by an authority to its subordinate agencies. These decrees are significant in as much as they make an impression on many legal subordinates outside the authority, including e.g. physicians. If a decree is ignored, disciplinary action may be taken, as has been shown. The admissibility of dispensation on the basis of § 12 Par. 1 (2), Austrian Drugs Act, is not mentioned. Therefore and based on further incidents, my legal counsel requested enlightenment on my behalf in a letter dated 15 July 2004 (Exhibit ./18). Although the fundamental applicability of § 12 Par. 1 (2) of the Austrian Drugs Act is conceded in the reply dated 3 September 2004, it is also said that this provision cannot be applied to Ukrain because medicinal products authorised in Austria were available. The general nature of this statement is incomprehensible for me. It is exclusively at the discretion of the attending physician to decide which therapy to use. Moreover, in therapy-refractory patients, i.e. patients abandoned by the orthodox school of medicine, it is all too obvious that no further treatment method authorised in Austria is available. Therefore this information is factually and legally incorrect.

In a letter dated 8 January 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 (Exhibit ./20). Thereby the Federal Institute exceeded its competences significantly.

For all the above-named reasons it is clear that I could never have expected a fair procedure before the authorisation authority. If the legal position were so clear, my application would have had to be rejected much earlier. Instead, I was strung along for decades. Therefore the thought suggests itself that the authority was trying to construct a case as resistant to appeal as possible, which the Administrative Court would not need to modify and upon which it could simply base its decision. I did not even have an influence on the appointed experts, which the authorisation authority was able to select entirely at its own discretion. Yet the expert reports by the experts Dr. Winkler and Dr. Robert formed the basis for the subsequent rejection of my application for authorisation. It certainly worked. Even the Administrative Court failed to deal with all the points of complaint and merely picked out one of them in its Finding dated 21 November 2005. Therefore my statement of the case was not dealt with in full.

4. Domestic Remedies Sought

The decision by the Administrative Court is final. There is no appeal against it. An appeal against the decision by the Federal Ministry of Social Security and Generations of 25 April 2002 before the Constitutional Court did not hold much promise of success from the start. The decision could only have been examined with regard to the violation of constitutionally guaranteed rights. The Constitutional Court cannot conduct a full-scope examination.

5. I submit the following documents:

Exhibit ./1	Power of Attorney
Exhibit ../2	Finding by the Administrative Court of 21.11.2005
Exhibit ../3	Complaint dated 7.6.2002
Exhibit ../4	Reply dated 12.12.2002

Exhibit ../5	Expert Report by Dr. Robert dated 28.12.2001
Exhibit ../6	Expert Report by Dr. Winkler dated 14.3.2002
Exhibit ../7	Summary of Investigations by the National Cancer Institute
Exhibit ../8	Summary of Product Characteristics Mabthera
Exhibit ../9	Summary of Product Characteristics Mabthera
Exhibit ../10	Statement on the Expert Report by Prof. Dr. Winkler dated 31.5.2002
Exhibit ../11	Expert Report by Dr. Tittel OHG dated 25.6.2001
Exhibit ../12	Text of § 12, Austrian Drugs Act
Exhibit ../13	Summons by the Disciplinary Board of the Austrian Medical Council dated 11.1.1996
Exhibit ../14	Documentation of disciplinary action against Dr. Langer
Exhibit ../15	Order by the Inland Revenue Office Urfahr dated 20.7.1998
Exhibit ../16	Decree by the Federal Ministry of Health and Environmental Protection dated 25.7.1986
Exhibit ../17	Circular issued by the Federation of Austrian Social Insurance Agencies dated 11.3.1994 and Decree by the Federal Ministry of Health, Sports and Consumer Protection dated 25.2.1994
Exhibit ../18	Letter from Schönherr Rechtsanwälte OEG dated 15.7.2004
Exhibit ../19	Letter from the Federal Ministry of Health and Women's Issues dated 3.9.2004
Exhibit ../20	Letter from the Federal Institute for Chemical and Pharmaceutical Testing dated 8.1.1998
Exhibit ../21	Expert Report by Dr. Robert dated 5.4.2001

Dipl.-Ing. DDr. Wassyl Nowicky