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Case No. 42755708

A02405-10/18

**JUDGMENT**

In the name of Latvian people

2 June 2010

Riga

District Court of Administrative Cases composed of:

Judge K. Kalvāne – Radziņa

With the participation of authorized representative of the Applicant I.S. - L.K. and the authorized representatives of the Defendant - the Republic of Latvia – A.R., the spokespersons of the Ministry of Health of the Republic of Latvia, and the authorized representative of Health Payment Centre – S.G.

In open court hearing reviewed the administrative case, which was prosecuted based on I.S. application to issue beneficial administrative that would establish full compensation of purchase costs of the medication *Sprycel* (dasatinib) for 13 packages (one package contains 56 pills).

## The facts

[1] On 29 August, 2008, Health Compulsory Insurance State Agency (now Health Payment Centre[1]; hereinafter – HCISA) passed a resolution No 4/1.1-10/5736 (see case file pages 17 - 21) to reject I.S. (hereinafter – the Plaintiff) claim to compensate *Sprycel* (dasatinib) (hereinafter - *Sprycel*) purchase costs.

On 23 October, 2008, the Ministry of Health of the Republic of Latvia (hereinafter - the Ministry of Health) passed a resolution No. V-01-20fiz-17/1132 that nullified the above mentioned HCISA resolution and stated that HCISA must review I.S. application (see pages 30 – 33 of the case file).

[1] [*Translator's remark.*]

[2] 26 November, 2008, HCISA passed a resolution No. 6/1.1-10/8047 to compensate purchase costs for 13 *Sprycel* packs for 12-month treatment course and stated that maximum compensation amount is LVL 10 000 (see pages 65 – 58 of the case file).

On 26 January, 2009, the Ministry of Health passed a resolution No. V-01-20fiz.17/54 establishing that HCISA resolution No. 6/1.1-10/8047 of 26 November, 2008, remains valid (see pages 130 - 135 of the case file).

[3] On 12 January, 2009, the representative of the Plaintiff clarified the claim stated in the application and appealed for issuing beneficial administrative act that would impose an obligation on the Ministry of Health to fully compensate purchase costs of 13 packs *Sprycel*.

The Plaintiff fortifies its claim by the following arguments:

[3.1] According to Riga Eastern Clinical University Hospital doctors council conclusion of 10 July, 2008, the effectiveness of *Sprycel* for treating the Plaintiff's condition is evident. The council states that from medical point of view the medical indications shows that it is required to continue treatment with *Sprycel*. The Plaintiff will not survive without treatment with *Sprycel*.

Taking into account the above mentioned, it can be concluded: as qualified medical care professionals have confirmed that treatment with *Sprycel* is effective, irreplaceable and required for the Plaintiff, the Ministry of Health had no reason to question the effectiveness of the aforementioned medicament and to pass a resolution stating that HCISA must review the case, thereby, the resolution is unlawful.

[3.2] The Plaintiff requires the treatment with *Sprycel* in order to maintain vital functions, and without this treatment the Plaintiff will die.

[3.3] Considering Clause 92.2 and 95 of the Cabinet of Ministers Regulations No. 899 on the procedures for compensating purchase costs of the medication and medical equipment for out-patient treatment (hereinafter – the Regulations No. 899), it can be concluded that if none of the reimbursable medicaments are not suitable for a person

to maintain his/her vital functions, HCISA shall pass a compulsory administrative act - resolution on compensating medicament purchase costs in accordance with the established amount in Appendix I of the Regulations No. 899. The established amount for compensating medicament purchase costs regarding Plaintiff's illness (diagnosis Z 98.4) should be fully reimbursed according to Appendix I of the Regulations No. 899.

As HCISA resolution states all required documents have been submitted under Clause 92 of the Regulations No. 899, and doctors council conclusions contain all the required information, it can be concluded that in compliance with Clause 95 of the Regulations No. 899 HCISA was obliged to issue compulsory administrative act to fully compensate *Sprycel* purchase costs.

[4] The Ministry of Health pointed out the following in the written statement it submitted to the Court:

[4.1] Article 111 of the Constitution of the Republic of Latvia states that the State protects people health and guarantees minimum health care for everyone . Thus the Constitution states that a fixed amount of health care services is paid by the State. This minimum is established by the Cabinet of Ministers Regulations No. 1046 on procedures for the organization and financing of health care and the Regulations No. 899. Moreover, the Regulations No. 899 establish allocating LVL 10 000 per year to patients as a compensation of medicaments that are not included in the reimbursable medicament list. Every year the State allocates funds for medicament compensation based on the State guaranteed minimum compensation amount.

The amount of the State funds for providing medicament reimbursement is in compliance with the compensation amount established by the Law. Allocating reimbursement larger than a guaranteed minimum to a patient may cause a threat to other patients by prohibiting them guarantees established in the Law.

[4.2] The Ministry of Health used the issue with medicament *Glivec* as an example. In accordance with the procedure for including medicaments in the reimbursable medicament C list *Glivec* in 2007 was paid from the State funds covering 37 patients, but the medicament manufacturer paid from its funds covering 4 patients. Taking into

account that at the end of 2007 two patients were waiting on the treatment with *Glivec*, in 2008 number of patients, whose treatment with *Glivec* is paid by the State, were increased to 38. At the same time the medicament manufacturer announced that in 2008 it will pay only for 1 patient treatment.

Thus treatment for 3 more patients should be paid by the State, and currently it is not possible due to the fact that amount of funds has not been increased since last year, and, therefore, compensation for these patients would be paid at the expense of other patients. Thereby, 3 patients are waiting on continuing the treatment with *Glivec*.

The Ministry of Health states that it is impossible to compensate medicament that is not included in the reimbursable medicament list and probably is unfounded from cost efficiency point (LVL 45 000 are required every year for compensating *Sprycel*, and this amount could be used for two patients requiring treatment with *Glivec*).

[4.3] Due to the insufficient funds medicament *Herceptin* for breast cancer treatment is not included in the reimbursable medicament list. This medicament has been evaluated, and it corresponds to therapeutic and cost efficiency measures. This medicament has not been included in the list, because it requires supplementary funds that have not been allocated this year. An approximate *Herceptin* cost per year for one patient is LVL 15 000, and 20 patients are waiting for the treatment.

[4.4] In pharmacies prescription drugs for LVL 130 million have been distributed in 2007. For medicament reimbursement LVL 61 million were allocated in 2008. It can be concluded that everything prescribed by doctors cannot be paid from the State funds, and limitations for medicament reimbursement should be established. The aforementioned also can be referred to individual compensations.

[4.5] In order to include a drug in the reimbursable medicament list a life span measurement is taken into account - how much the particular drug prolong life in comparison to other available treatment (usually widely available treatment). Moreover, it is calculated how much the new treatment costs more than previous. Considering the odds of life span measurement and costs, incremental cost-effectiveness ratio (ICER) is calculated. Not only in Latvia is this ratio used while

creating the State reimbursable medicament list. Besides every country establish officially or unofficially the limit, i.e., how much a country is planning to pay for one acquired year of life. On average in Europe it is EUR 30 000, in Latvia it is LVL 28 000, which is the ratio of the most expensive medicament *Glivec* (average life span is 3.44 years). According to the Sub-clause 46.2 of the Regulations No. 899, in the reimbursable medicaments C list those drugs shall not be included which ICER is higher than the cost ratio of those drugs already included in the list.

Data presented at 12th Congress of European Haematology Association indicates that after 18.5 month of observation (since the moment treatment with dasatinib was started) for patients, who had stem cells transplantation, average life span was 9 month. After a year 22% of patients, who took part in the research, were alive and the illness stopped progressing.

[4.6] The Ministry of Health does not protest against doctor's right to prescribe medicaments he/she considers necessary for treating a particular patient, however, the State obtains an obligation to act according to the Law (Law on the State's budget for a particular year, as well as the Regulations No. 899) in order to guarantee that one patient interests does not subtract options from other patients to receive the State's help.

[5] HCISA pointed out the following in the written statement it submitted to the Court:

[5.1] HCISA has received the State Agency of Medicines letter No. 4-29/1343 "About medicament price" establishing that the declared price in the territory of the Republic of Latvia without VAT for pharmaceutical company's Bristol-Myers Squibb , France, manufactured *Sprycel* 70 mg N60 coated pills is LVL 4 797.90.

In accordance with the Clause 103 of the Regulations No. 899, if a price for a medicament has been declared in the territory of the Republic of Latvia, then the amount of medicament reimbursement is calculated pursuant to the Clause 26 and 28 of the Regulations No. 899. Therefore, the price a pharmacy could sell one package of *Sprycel* after 1 January, 2009, is LVL 5 493.48 after calculating the following: adding

the wholesale mark-up to the declared price then multiplying it by correction index and then adding corrected sum and the 10% VAT according to the Clause 26 and 28 of the Regulations No. 899. The Plaintiff's co-payment, therefore, is increasing by every *Sprycel* package.

[5.2] On 29 December, 2008, the Constitutional Court passed a judgment in Case No. 2008-37-03 whereby established Section 100 and $100^1$ of the Regulations No. 899 in compliance with Article 91 of the Constitution. The judgment came into effect on the day it was announced, i.e., on 30 December, 2008. Taken into considerations the aforementioned, HCISA decision No. 6/1.1-10/8047 is lawful, and the Plaintiff's right to receive compensation for medication purchase costs was not limited unlawfully.

[6] The representative of the Plaintiff based the application upon arguments established in the particular application.

[7] The representatives of the Defendant did not acknowledged the application on the ground of arguments established in the Decision and explanations submitted to the Court.

**Motivation part**

[8] The Court declines the application after hearing the Plaintiff's and the Defendant's statements, evaluating circumstances and evidence of the Case.

[9] The procedure on compensating medication purchase costs for individuals has been established in the legal norms of the Regulations No. 899. Those Regulations have been adopted on the grounds of Clause 20 of Section 5 of the Pharmaceutical Law.

The Clause 20 of Section 5 of the Pharmaceutical Law states the Cabinet's competence to establish the procedure for compensating purchase costs of the medication and medical equipment for out-patient treatment.

First of all, the Cabinet by adopting the Regulations No. 899 has established the basic principles for the compensation procedure stating that a patient shall receive a compensation for purchase costs of medication included in the reimbursable medicament list if a patient has been diagnosed with an illness included in the Appendix I of the Regulations No.899 upon characteristics and severity of illness and established compensation restrictions and prescription terms. Second of all, it is established that medication purchase costs are compensated in compliance with eligible compensation categories.

Sub-clause 4.1 of the Regulations No. 899 states that the Category I shall receive full compensation if a patient has been diagnosed with chronic, life-threatening illness or illness causing severe permanent disability requiring respective medicament treatment course in order to maintain patient's life functions. Further precision of the declared basic principles of Regulation No. 899 is included in legal norms that states medicament inclusion in the reimbursable medicament list, as well as establish procedure on compensation for purchase costs of the medication and medical equipment for individuals.

[10] Regarding persons that are not eligible for receiving medicament purchase cost compensation due to the fact that their diagnose is not included in the Appendix I of the Regulations No. 899 or none of the included medicaments in the reimbursable medicament list are suitable for maintaining life functions, the Cabinet has adopted special regulation included in the Chapter XII of the Regulations No. 899.

Sub-clause 92.2 of the Regulations No. 899 states that HCISA is authorized to make a decision about compensating purchase costs of the medication and medical equipment for individuals on the grounds of person's application with enclosed doctors council's decision. The aforementioned purchase costs are compensated within the funds granted for such compensations if the diagnosis is included in the Annex I of the Regulations No. 899 and none of the reimbursable medicaments or medical equipment are applicable (such medicaments or medical equipment is required that are not included in Reimbursable Medicament list for the particular diagnosis).

However, Clause 95 of the Regulations No.899 states the volume and restrictions regarding compensation of medicament purchase costs that is established in Clause $100^1$.

Clause $100^1$ of the Regulations No. 899 states that if the planned costs exceed established costs in the Clause 100 of those regulations, then HCISA indicates in its decision the amount of compensation for one medicament package (..). Clause 100 of those regulations establishes that in the particularly stated cases the maximum compensation amount for 12-month treatment course that HCISA shall grant for one patient is LVL 10 000 (the compensation for purchase costs of the medication and medical equipment for individuals).

By reviewing the particular legal norms in general (systematically interpreting them), it can be concluded that the Cabinet has adopted a restriction for compensation of medication and medical equipment purchase costs for individuals no more than LVL 10 000 for 12 months.

[11] In the particular case a dispute exists whether the restriction of Clause 100 of the Regulations No. 899, establishing the limit for such compensation, and Clause $100^1$ of those regulations, establishing the procedure for estimating the compensation, are applicable while granting the compensation to the Plaintiff.

The Plaintiff states that her/his case is not a typical case, therefore, the limit established in the Regulations No. 899 is not applicable due to the fact that *Sprycel* is very effective for treating Plaintiff's illness.

The Cabinet has established that within the granted State's funds the maximum amount for a compensation for one patient, emerging from Sub-clause 92.2, Clause 95, 100 and $100^1$ of the Regulations No. 899, in any case for individuals is no more than LVL 10 000 for 12 months

Thus, on the grounds of legal norms established by the Regulations No. 899, the Defendant has acted legally and reasonably, while calculating and estimating the amount of compensation for the Plaintiff.

[13] In the legal literature, commenting on Constitutional Court decision in case No. 2006-41-01 of 28 February, 2007, that confers a right for district courts to review the suitability of issuing compulsory administrative act in case of atypical cases, is stated that if an institution does not have a right to act freely and shall issue a compulsory administrative act, and an institution has formally and correctly applied legal norms and issued such administrative act that is in compliance with legal norms, but it is disproportionate, i.e., the restriction for an individual is too severe in comparison with the benefit society will gain from, then it is the fault of Legislator not the institution. (Egils Levits, *Prof. Dr. ju. h. c. Ass. jur. Dipl.Pol.,* European Community judge. Proportionality principle and mandatory administrative act, published in *"Jurista Vārds"*, 27th March, 2007, issue No 13).

Two ways exists to correct Legislator's errors in accordance with Latvian judicial system and the aforementioned Constitutional Court decision.

If Legislator as judicial consequences establish mandatory, however disproportionate, administrative act for a case that comply with the situation provided in the judicial norms (a typical case), then in accordance with Latvian judicial system such error may be corrected by the Constitutional Court, which evaluates compliance of a particular norm with the Law . In that case the Constitutional Court declares invalid such Law (or other laws and regulations).

However, Administrative Court is entitled to correct Legislator's error and to forestall the passing of compulsory administrative act established by the Law if it causes violation of proportionality principles in atypical cases (Egils Levits, *Prof. Dr. ju. h. c. Ass. jur. Dipl.Pol.,* European Community judge. Proportionality principle and mandatory administrative act published in *"Jurista Vārds"*, 27th March, 2007, issue No 13).

[14] Therefore, judicial consequences other than established by Clause 100 and $100^1$ of the Regulations No. 899 may be used in the particular case only if it is an atypical case.

An atypical case is a case that complies with all judicial requirements for legal norms, however, additional circumstances are indissolubly related to it and they are significantly altering the character of that case. Legislator has not unwittingly included atypical cases in legal norms because it could not anticipate them (if they would be anticipated, then they would be included in the defining of a typical case), therefore, regarding atypical cases Legislator has not considered proportionality principles and has not included them in judicial requirements for legal norms. *(*Egils Levits, *Prof. Dr. ju. h. c. Ass. jur. Dipl.Pol.,* European Community judge. Proportionality principle and mandatory administrative act published in *"Jurista Vārds"*, 27th March, 2007, issue No 13*)*

The Court holds that Plaintiff's stated circumstances are not sufficient enough to form a ground for atypical case, namely, such case that Legislator has not covered with judicial framework of Clause 100 and $100^1$ of the Regulations No. 899.

[15] Different age groups are under the risk to become ill with diseases, including severe life-threatening diseases. Also lack of money should be considered as a typical case in current social-economic circumstances. As well as the lack of money may be considered as a typical case and not an exception. In addition, in some cases the medicament price are too high, therefore 10 00 LVL compensations for 12 month treatment does not cover it.

Wherewith the particular circumstances cannot be outside Legislator's scope, therefore, it is unfounded to assume that the particular case is atypical and judicial composition of Clause 100 and $100^1$ of the Regulations No. 899 does not cover it. Namely, the Cabinet could anticipate, while adopting the Regulations No. 899, that with 10 000 LVL compensation might not be sufficient to fully cover medicament purchase costs for all patients requiring special medication that are not included in the reimbursable medicament list. On the contrary, the Cabinet has anticipated it and acted accordingly its competence in budget planning and allocation referable to health protection field, taking into account State funding allocation that so they would most used most efficiently – would be sufficient enough for the largest number of patients possible requiring medication purchase costs compensation.

Moreover, it can be concluded from the HCISA submitted information that in 2008 10 persons have submitted application for compensation and the purchase costs exceed the established compensation limit of 10 000 LVL in the Regulations No. 899(case file pages 65 – 67, volume II).

[16] By reviewing a similar claim, the Administrative Court submitted an application to the Constitutional Court on Clause 100 and 1001 of the Regulations No. 899 compliance with Article 91 of the Constitution.

The Constitutional Court's decision of 29 December, 2009, on case No. 2008-37-03 stated that Clause 100 and 1001 of the Regulations No. 899 are in compliance with Article 91 of the Constitution.

The Constitutional Court holds in the above mentioned decision that the impugned regulations contain justified attitude and as the different attitude has a legitimate cause and the proportionality principle is taken into account, the impugned regulations comply with Article 91 of the Constitution.

According to Section 5 of Clause 17 of Administrative Procedure Law if the Constitutional Court has interpreted the particular legal regulation in the judgment, the institution and court applies that legal regulation and according to Second Sentence of Section 2 of Clause 104 of Administrative Procedure Law the Court that submitted the application while reviewing particular case repose on the decision of the Constitutional Court.

Reviewing the case by its nature? The Administrative Court declined the Plaintiff's application by decision of 23 March, 2009 (case No. A42687407). The judgment has entered into force legally.

[17] As the Constructional Court established in the decision of 29 December, 2008, in case No. 2008-37-03 the State by adopting such exceptional legal regulation regarding compensation of medicament purchase costs for individuals has a large freedom of action deciding about funding allocation (..) Wherewith it can be concluded that the

State may have the right to not compensate purchase costs of such medicaments that therapeutic and costs efficiency is not sufficient or not proven. The State, however, has decided for providing such support to persons requiring that medication, although, providing it in limited amount (see Clause 12.3 of the Constitutional Court decision of 29 December, 2008, in case No. 2008-37-03).

The Constitutional Court on 7 January, 2010, decided that Article 93 and 110 of the Constitution of the Republic of Latvia comply with the Clause 92 second sentence's words "within the granted limits of medication purchase", Clause 94's words "with the exception of mentioned case in the Regulation Paragraph $100^{1}$", Clause 100's words "not more than the amount of LVL 10 000 for one patient in 12 months" and the second sentence of Clause $100^{1}$ of the Cabinet of Ministers Regulations No. 899. The Constitutional Court acknowledged that the limited compensation amount - LVL 10 000 for 12 month period – is established by evaluating the State budget options. (see the Constitutional Court Judgment of 7 January, 2010, in case No. *2009*-12-03)

Taking into account the aforementioned the Court holds that the Plaintiff's case cannot be acknowledged as such so institutions or court could deviate from laws and regulations establishing the procedure on medicament purchase cost compensation for individuals and decide on full Medicament purchase cost compensation.

[18] At the same time the Court holds that the patient's ability to cover the required amount of medicament purchase costs depends on the person's financial status. It also should be taken into account that the State has established the 10 000 LVL for 12 month period compensation amount limit on the grounds of its budget options not on patient's financial status, but by evaluating the budget options it aimed to achieve the most efficient way of allocating budget for medicament compensation system in order to provide as large part of society as possible right to health.

The content of right to health includes the negative State's obligation (not to kill persons unless it is exceptionally required) and the positive obligation (to do everything possible to protect person's life from wilful action of the State's representatives as well as from criminal intentions). Objectively the State cannot be liable for person's illness and natural consequences caused by it.

The Constitutional Court has indicated in the judgment of 7 January, 2010, that a questionable issue for legal scholars is if and to what degree Clause of the Convention (The European Convention on Human Rights) apply to the State obligation to protect life in case when life is threatened by external circumstances, i.e., illness or environmental factors, namely, requesting implementation of such activities relates to provision of sufficient medical help, traffic safety or prevention of significant environmental pollution. From the history of how the Convention and Article 2 was made it can be concluded that the provision with social rights wasn't established in it. Therefore, the State's has obligation to carry out some actions according to Clause 2 of the Convention only the life threatening is urgent and specific.

However, the difference between term "maintaining life functions" within the concept of Regulations No 899 and term "specific and urgent life threat" within the concept of Article 2 the Convention. Laws and regulations do not guarantee a specific number of years for a person to live. None of countries can do that. A person's life span is affected not only by available medicaments, but also many other factors like healthy or unhealthy diet, sleep, stress, environment. However, while evaluating activities the State carries out in this area, it should be taken into account that not every activity affecting person's life span could automatically be regarded as right to life. (see the Administrative District Court Judgment of 19 May, 2010, in case No. A420558510)

[19] In the judgment of 7 January, 2010, the Constitutional Court has acknowledged that the actions of government institutions in the particular case comply with Article 110 and 110 of the Constitution established basic rights and judicial country principles is possible to answer only by evaluating this case's specific circumstances including possible severity of consequences and irreversibility regarding a person's health, also alternative funding options and other circumstances.

From the aforementioned judgment can be concluded that if the State does not fully compensate medication then it does not mean a person definitely will not be able to purchase them. The State has implemented legal system that allows a person to approach another person for help. According to Clause 2 of Public Benefit Organisation Law on operating public benefit such action that is intended to promote

health and prevent illness is acknowledgeable. Persons donating money to charity are entitled to receive tax allowances established by the Law (see the Constitutional Court Judgment of 7 January, 2010, in case No. 2009-12-03).

Wherewith, evaluating actual facts in the particular case, the Court concludes that the Plaintiff has not fully used options to receive uncompensated part of purchase costs from the manufacturer. On 31 October, 2007, the Plaintiff sent a letter to Bristol-Myers Squibb Eesti (case file pages 62 – 63, volume II), although, the medicament manufacturing licence holder Bristol-Myers Squibb is located in France or Bristol-Myers Squibb S.r.l in Italy (the medicament manufacturing licence holder in Europe depending on product line, http://www.ema.europa.eu/humandocs/PDFs/EPAR/sprycel/emea-combined-h709lv.pdf, July 1st, 2010). Therefore, the Plaintiff has not approached the direct medicament manufacturing licence holder in Europe. In addition, as the Plaintiff has stated she/he has not received a reply to the letter and has not resubmitted a claim to compensate medicament purchase costs not covered by the State. The Court holds that the Plaintiff has not been active in order to fulfil his/her interests in order to attain proportionality between personal and State finances. Moreover, the Plaintiff knew the State's laws and regulations on limitations of medicament purchase cost compensation. Wherewith, the Plaintiff could not rely on the fact that he/she will purchase *Sprycel* without co-payment.

The Court holds that the therapy with *Sprycel* is efficient to the Plaintiff proved by medical analysis (case file pages 56 – 61, volume II) and Dr. I.T. submitted information (case file page 55, volume II). However, an answer has not been given about the irreversible damages on the Plaintiff's health and life, as well as about the development speed if the *Sprycel* treatment has not been received. Wherewith, the Court cannot evaluate about possible severity of consequences that might arise if the Plaintiff will not receive the *Sprycel* therapy.

Moreover, as the Court has indicated previously the Plaintiff can receive alternative funding from public benefit organisations or by approaching the medicament manufacturing licence holder in Europe. As the case does not contain any proof of alternative funding refusal the Court cannot consider that the Plaintiff has been fully

restricted from receiving required medication. Hereby in the particular case the Court does not distinguish the fact that the Plaintiff will not be provided with the rights guaranteed under the Constitution or violated judicial country principles by not compensating medicament purchase costs from the State budget.

[20] Taking into account the above mentioned the Court holds that the Plaintiff's application on issuing a beneficial administrative act is ungrounded and shall be declined.

**Adjudication**

Based on Clause 246 - 251 of the Administrative Procedure Law, District Court of Administrative Cases

**rules:**

to decline I.S. application on issuing a beneficial administrative act by which I.S. would receive a 100% compensation for *Sprycel* (dasatinib) purchase costs for 13 packages (one package contains 56 pills).

The judgment is subject to appeal in District Court of Administrative Cases in 20 days time since its been composed by submitting a appellation claim to Administrative Regional Court in Riga Court house.

The judgment is composed on 2 June, 2010.

Judge (*signature*) K. Kalvāne-Radziņa

TRUE COPY OF THE ORIGINAL
District Court of Administrative Cases Judge

K. Kalvāne-Radziņa
Riga, 2 June 2010