Eidgenössisches Institut für Geistiges Eigentum
Institut Fédéral de la Propriété Intellectuelle
Istituto Federale della Proprietà Intellettuale
Swiss Federal Institute of Intellectual Property

Research and Patenting in Biotechnology

A Survey in Switzerland

Publikation / Publication No 1 (12.03)

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Foreword

Innovation is the operative condition for increasing added value. This implicates the intellectual property system because through intellectual property rights, investment in innovative projects is encouraged and rewarded. This applies in particular for the biotechnology industry.

The report presents the results of a survey with the Swiss biotechnology industry, conducted by the Swiss Federal Institute of Intellectual Property in 2003. The survey was a consequence of the Swiss Federal Council's decision, on December 7, 2001, to hold a public consultation regarding the preliminary draft of the partial revision of the Swiss patent law. [1] This consultation marked the beginning of a public discussion about patenting of biotechnological inventions in Switzerland. The consultation revealed, among other things, that there is a general lack of empirical evidence on this topic. The Federal Council therefore requested the Swiss Federal Institute of Intellectual Property to analyze certain issues which came up in the opinion-gathering more in detail. Two areas which were investigated in detail are presented in this report, namely:

- The impact of patents (in particular gene patents) on biotechnological inventions in basic and applied research;
- The economic implications of patents (in particular gene patents) for biotechnological inventions.

This report presents and discusses the results of two survey questionnaires. It provides a representative perspective of the Swiss biotechnology industry on research and patenting in biotechnology. The aim of the report is to encourage public discussion on biotechnology patents in Switzerland with regard to the current revision of the Swiss patent law. Its objective is also to provide an important contribution to the international debate on biotechnology patents. It is my hope that this report will stimulate the dialog on patenting of biotechnological inventions in an objective and constructive way.

In the name of the Swiss Federal Institute of Intellectual Property I would like to express my gratitude to all the industry representatives and representatives from research institutes and universities who participated in the two surveys. Without their valuable contributions this report would not have been possible.

Roland Grossenbacher
Director of the Swiss Federal Institute of Intellectual Property

[1] Cf. http://www.ige.ch/E/jurinfo/j100.htm#2

Vorwort

Innovation ist eine operative Bedingung für die Schaffung von volkswirtschaftlichem Nutzen. Dies impliziert ein System geistiger Schutzrechte. Durch Immaterialgüterrechte werden Investitionen für innovative Projekte anregt und belohnt. Dies gilt insbesondere in der Biotechnologieindustrie.

Dieser Bericht stellt die Ergebnisse einer Befragung mit der Schweizer Biotechnologieindustrie vor, die das Eidgenössische Institut für Geistiges Eigentum im Jahr 2003 durchgeführt hat. Die Befragung war eine Konsequenz der Entscheidung des Bundesrates vom 7. Dezember 2001, eine Vernehmlassung zum Entwurf der Teilrevision des Patentgesetzes in der Schweiz durchzuführen[2]. Diese Vernehmlassung markierte den Beginn einer öffentlichen Diskussion über Patentierung von biotechnologischen Erfindungen in der Schweiz. Die Vernehmlassung zeigte unter anderem, dass es an empirischen Daten zu dieser Diskussion fehlt. Der Bundesrat forderte daher das Eidgenössische Institut für Geistiges Eigentum auf, bestimmte Gebiete, die bei der Vernehmlassung als kritisch erachtet wurden im Detail zu untersuchen. Zwei dieser Gebiete werden in diesem Bericht behandelt, namentlich:

- Der Einfluss von Patenten (insbesondere Genpatente) auf biotechnologische Erfindungen der Grundlagenforschung und der angewandten Forschung;
- Die ökonomischen Auswirkungen von Patenten (insbesondere Genpatente) für biotechnologische Erfindungen.

Der vorliegende Bericht präsentiert und diskutiert die Ergebnisse der Auswertung zweier Fragebögen. Er stellt ein repräsentatives Meinungsbild der Schweizer Biotechnologieindustrie zu Forschung und Patentierung in der Biotechnologie vor. Ziel ist es mit Hinblick auf die laufende Teilrevision des Schweizer Patentrechts die öffentliche Diskussion zu Patenten in der Biotechnologie anzuregen. Ferner soll der Bericht einen wichtigen Beitrag zur internationalen Diskussion über biotechnologische Patente liefern. Ich hoffe sehr, dass dieser Bericht den Dialog über Patentierung biotechnologischer Erfindungen in einer objektiven und konstruktiven Weise anregen wird.

Im Namen des Eidgenössischen Institutes für Geistiges Eigentum möchte ich meinen Dank aussprechen an all diejenigen Vertreter von Schweizer Biotechnologiefirmen und von Schweizer Forschungseinrichtungen und Hochschulen, die an der dieser Studie zugrunde liegenden Befragung teilgenommen haben. Ohne ihre wertvollen Beiträge wäre dieser Bericht nicht möglich gewesen.

Roland Grossenbacher
Direktor des Eidgenössischen Instituts für Geistiges Eigentum

[2] Cf. http://www.ige.ch/D/jurinfo/j100.htm#2

Avant-propos

L'accroissement de la valeur ajoutée est tributaire des innovations. Or qui dit innovations, dit propriété intellectuelle. Véritable récompense, les droits de propriété intellectuelle stimulent les investissements dans les innovations, en particulier les innovations biotechnologiques.

Le présent rapport expose les résultats d'une enquête menée par l'Institut Fédéral de la Propriété Intellectuelle (Institut) en 2003 auprès d'entreprises privées et d'instituts de recherche du secteur biotechnologique. Cette enquête a été menée, sur décision du Conseil fédéral le 7 décembre 2001, à la suite de la procédure de consultation sur l'avant-projet de révision partielle de la loi fédérale sur les brevets d'invention.[3] Cette consultation a lancé le débat sur la brevetabilité des inventions biotechnologiques en Suisse. Elle a révélé, entre autres, qu'il existait très peu de connaissances empiriques sur le sujet. Le Conseil fédéral a donc demandé à l'Institut d'approfondir certaines questions soulevées lors de la consultation. Deux aspects examinés de manière approfondie dans le cadre de l'enquête sont traités dans ce rapport:

- l'impact des brevets biotechnologiques (en particulier des brevets dits génétiques) sur la recherche fondamentale et la recherche appliquée;
- les enjeux économiques des brevets biotechnologiques (plus particulièrement des brevets génétiques).

L'enquête menée par l'Institut était constituée de deux questionnaires. Le présent rapport résume et commente les réponses fournies aux questions posées et offre ainsi une image représentative de l'avis de l'industrie biotechnologique sur la recherche et les brevets relatifs aux inventions biotechnologiques. Le rapport poursuit deux objectifs :d'une part, alimenter le débat sur ce thème en Suisse eu égard à la révision actuelle de la loi sur les brevets et d'autre part, enrichir la discussion menée au niveau international sur les brevets biotechnologiques. J'espère donc que ce rapport apportera une contribution constructive et objective à la discussion sur le sujet.

Au nom de l'Institut, je souhaite adresser mes sincères remerciements à l'ensemble des entreprises biotechnologiques, aux instituts de recherche et aux universités qui ont participé à l'enquête. Sans leur précieuse contribution et coopération, l'Institut n'aurait pas été en mesure de publier ce rapport.

Roland Grossenbacher
Directeur de l'Institut Fédéral de la Propriété Intellectuelle

[3] Cf. http://www.ige.ch/F/jurinfo/j100.htm#2

Executive summary

After information technology, biotechnology is expected to be the next wave of the knowledge-based economy, creating new opportunities for society and the economy in the third millennium. Its potential applications promise to be a growing source of wealth creation in the future, leading to the creation of jobs, many of which will be highly skilled, and new opportunities for investment in further research. Protection of intellectual property is one of the core issues for biotechnology firms. High investment costs and the ease with which results can be copied make the biotechnology industry particularly sensitive to the issue of intellectual property.

Switzerland is one of the few countries in Europe where the recent slow-down in industrial biotechnology development had almost no effect. Switzerland has the second highest number, after Sweden, of independent, dedicated biotechnology firms per inhabitant in Europe. Biotechnology is a global market and Swiss companies think globally.

In November 2002, the Swiss Federal Council accepted the summary report on the outcome of the public consulting procedure for the partial revision of the patent law in Switzerland. Before presenting the report to the Parliament, the Federal Council asked the Federal Ministry of Justice and Police to investigate certain issues in more detail. The Swiss Federal Institute of Intellectual Property (under the Ministry of Justice) prepared two survey questionnaires asking research institutes and private companies in the field of biotechnology about their positions on problematic issues in biotechnology research and patenting.

The survey had four objectives: First, to come to a better understanding of the economic aspects of patenting in the field; second, to achieve an understanding of the concrete practical problems; third, to find out shortcomings within the current Swiss legislation; fourth, to obtain a reliable empirical basis for the ongoing partial revision of the patent law in Switzerland. Finally, the EU directive 98/44/EC on the legal protection of biotechnological inventions in Switzerland served as an important background to the investigation.

One particular focus of the study is the issue of patents and their influence on access to research. To what extent do patents in the field of biotechnology limit the dissemination of technological knowledge, when and under which circumstances? The aim of this study is to indicate possible policy conclusions concerning intellectual property rights in response to the needs of Swiss biotechnology companies and institutes. It takes into account the need to provide recognition and incentives for research, invention and exploitation, to encourage competition and to meet the needs of current and future users of creative work and its products.

In February 2003, the Swiss Federal Institute of Intellectual Property sent out 200 questionnaires to research institutes and private companies. By the end of March 2003, 53 completed questionnaires had been returned. A second questionnaire was mailed in August and evaluated in September 2003. The most important findings are the following:

- Survey participants confirm that the patent system is an important incentive for investment in research and development in the field of biotechnology.
- Patents and licenses for biotechnological inventions are considered an important incentive to stimulate research, knowledge flows and the entry of new technologies into markets.
- Switzerland files more triadic patent applications (those applications filed at the EPO, the USPTO and the Japanese Patent Office) per inhabitant than any other country in the world. Swiss biotechnology patenting performance indicates that the Swiss biotechnology industry is closely linked to other countries, especially the United States.
- The Swiss biotechnology industry is one of the strongest in Europe. It is a very research-and-development intensive branch with high growth rates and a high potential for innovation. In addition, the industry shows increasing numbers of patent applications. Small companies in the sample show the highest potential for innovation in terms of patenting per employee in research and development.
- Biotechnology companies wish to resolve the unclear legal situation with biotechnological inventions in the European Union and in Switzerland (particularly compared to the USA) and, consequently, welcome the implementation of the European directive on biotechnological inventions in Switzerland.
- Patents, secrecy and lead-time advantages, play an important role as protection mechanism for inventions. Big companies and some small and medium-sized companies use patents intensively.
- Main motives to abstain from seeking patent protection are, (1) patents are considered to be too expensive and (2) that patent protection requires the full disclosure of the invention made.
- Patent litigation plays a minor role in Switzerland.
- Traditional uses of patents (the evaluation of the state-of-the-art in a technological field together with a purely defensive patenting strategy to protect one's own technology), dominate in Switzerland.
- With respect to licensing, the survey participants, and in particular research institutes, would welcome a compulsory licensing regulation in those cases where abusive monopoly positions are apparent.
- Moderate problems involving DNA patents were identified as: (1) dependency on previous patents (crowded art); (2) patents that lock access to technologies; and (3) difficulties to enter a technological field because of too many patents and conflicts with overlapping patents.
- Participants consider a broad research exemption and a limitation of the scope of protection of DNA patents to the specific disclosed functions as possible solutions to the problems with DNA patents. Survey participants believe that an 'absolute' scope of protection for DNA patents would hamper research as well as further development. However, a concrete disclosure of the function of DNA patents would enable the restriction of patent claims.

- Survey participants raise concerns that the implementation of a research exemption in Switzerland should not be undermined by Material Transfer Agreements (MTA).
- Survey participants in general do not believe that the introduction of a grace period would be an efficient remedy to overcome shortcomings with DNA patents.
- Participants feel that patents on methods for genetic testing can lead to over-strong monopoly positions. Patents can increase the costs of genetic testing methods - there have been cases where this has led to the non development of new testing methods.
- In order to overcome the problems with genetic testing patents, the survey participants suggest that efficient remedies would be a clinical use exemption and offering clinical laboratories non-exclusive licenses for patented genetic test on reasonable terms.

A detailed summary with all findings of the surveys and the conclusions of the study can be found at the end of the report. The Report 'Research and Patenting in Biotechnology; A Survey in Switzerland' is electronically available under http://www.ige.ch/E/jurinfo/j100.htm#2

Zusammenfassung

Es wird davon ausgegangen, dass Biotechnologie nach der Informationstechnologie die nächste bahnbrechende Technologie der Wissensbasierten Gesellschaft sein wird und dass sie grossartige Möglichkeiten für die Gesellschaft und die Wirtschaft des dritten Jahrtausends hervorbringen wird. Ihre potentiellen Anwendungen versprechen eine anhaltende Quelle von Wohlfahrt in der Zukunft, die zu vielen höher qualifizierten Arbeitsplätzen und neuen Investitionsmöglichkeiten für die Forschung führen wird. Der Schutz geistigen Eigentums ist eines der zentralen Anliegen von Biotechnologiefirmen. Hohe Investitionskosten und die Leichtigkeit mit der Forschungsergebnisse kopiert werden können machen die biotechnologische Industrie besonders sensible für Fragen des Immaterialgüterrechtschutzes.

Die Schweiz ist eines der wenigen Länder in Europa in dem der vor kurzem aufgetretene Wachstumsrückgang der Biotechnologie sich nahezu nicht auswirkte. Nach Schweden hat die Schweiz hat die zweithöchste Anzahl von Biotechnologiefirmen pro Einwohner in Europa. Biotechnologie ist ein weltweiter Markt und Schweizer Unternehmen denken global.

Im November 2002 akzeptierte der Schweizer Bundesrat den Zusammenfassungsbericht der Ergebnisse aus der Vernehmlassung der Teilrevision des Patentgesetzes in der Schweiz. Der Bundesrat forderte das Eidgenössische Justiz- und Polizeidepartement (EJPD) auf, bestimmte Fragestellungen zu vertiefen, bevor der Bericht vor das Parlament gebracht wird. Das Eidgenössische Institut für Geistiges Eigentum erarbeitete zwei Fragebögen mithilfe derer Forschungseinrichtungen und private Firmen aus der Biotechnologie Stellung beziehen konnten zu problematischen Fragestellungen der Patentierung von biotechnologischen Forschungsergebnissen.

Die Umfrage hatte vier Ziele: erstens, zu einem besseren Verständnis der ökonomischen Aspekte von Patentierung in diesem Bereich zu gelangen; zweitens, ein Verständnis der konkreten praktischen Probleme zu bekommen; drittens, Unzulänglichkeiten der Schweizer Gesetzgebung herauszufinden; viertens, zu einer verlässlichen empirischen Basis für die laufende Teilrevision des Schweizer Patentrechts zu kommen. Schliesslich, diente die EU Richtlinie 98/44/EC für den Schutz biotechnologischer Erfindungen als wichtiger Hintergrund der Untersuchung.

Ein spezieller Fokus der Studie ist die Fragestellung, welchen Einfluss Patente auf den Zugang zu Forschungsergebnissen haben. Können Patente der biotechnologischen Forschung die Diffusion technologischen Wissens behindern, wann und unter welchen Voraussetzungen? Die Absicht dieser Studie ist es, als Antwort auf die Bedürfnisse Schweizer Biotechnologiefirmen und Forschungseinrichtungen, bestimmte Politikempfehlungen bezüglich geistiger Eigentumsrechte geben zu können. Dabei werden insbesondere die Notwendigkeit von Patenten Anerkennung und Anreize für Forschung, Erfindungen und ihre Nutzung zu geben, der Anreiz zu Wettbewerb und die Notwenigkeiten gegenwärtiger und zukünftiger kreativer Arbeit und ihrer Produkte berücksichtigt.

Im Februar 2003 verschickte das Eidgenössische Institut für Geistiges Eigentum 200 Fragebögen an Firmen und Forschungseinrichtungen. Bis März 2003 waren 54 ausgefüllte Fragebögen eingegangen. Ein zweiter Fragebogen wurde im August

2003 verschickt und bis September ausgewertet. Folgende sind die wichtigsten Ergebnisse der Befragung:

- Die Teilnehmer der Umfrage bestätigen, dass für die Biotechnologie das Patentsystem ein wichtiger Anreiz ist für Investitionen in Forschung und Entwicklung.
- Patente und Lizenzen für biotechnologische Erfindungen werden als wichtiger Anreiz betrachtet für die Stimulation der Forschung, für die Verbreitung von Wissen und für den Eintritt von neuen Technologien in Märkte.
- Die Schweiz meldet weltweit am meisten Triade-Patente pro Einwohner an (Patente, die am Europäischen, Amerikanischen und Japanischen Patentamt angemeldet werden). Die Entwicklung der Biotechnologiepatente in der Schweiz zeigt, dass die Schweizer Biotechnologie sehr eng mit den Industrien anderer Länder verbunden ist, insbesondere den USA.
- Die Schweizer Biotechnologieindustrie ist eine der stärksten in Europa. Die Biotechnologie ist eine sehr forschungs- und entwicklungsintensive Branche mit hohen Wachstumszahlen und einem hohen Innovationspotential. Die Industrie zeigt steigende Zahlen von Patentanmeldungen. Kleine Firmen zeigen das höchste Innovationspotential gemessen an Patenten pro Mitarbeitern, die in der Forschung und Entwicklung arbeiten.
- Biotechnologiefirmen möchten die unklare rechtliche Situation bzgl. biotechnologischer Erfindungen in der Europäischen Union und der Schweiz (insbesondere im Vergleich mit den USA) geregelt wissen. Folglich heissen sie die Angleichung des Schweizer Patentrechts an die Europäische Richtlinie für den Schutz biotechnologischer Erfindungen willkommen.
- Patente, Geheimhaltung und Marktvorteile durch Zeitvorsprung spielen eine wichtige Rolle als Schutzmechanismus für Erfindungen. Grosse Unternehmen und einige kleine und mittlere Unternehmen (KMU) nutzen die Patentierung intensivst.
- Als Hauptgründe von der Patentierung Abstand zu nehmen, wurden erwähnt, dass Patente zu teuer seien und dass sie die volle Offenlegung der Erfindung erfordern.
- Patentstreitigkeiten spielen eine geringe Rolle in der Schweiz.
- Traditionelle Verwendungen von Patenten (die Evaluierung des aktuellen Stands der Technik in Verbindung mit einer defensiven Patentstrategie zum Schutz eigener Technologien) überwiegen in der Schweiz.
- Die Teilnehmer der Befragung, insbesondere von Seiten der Forschungseinrichtungen, würden eine Regulierung von Zwangslizenzen dort begrüssen, wo ein Missbrauch einer marktbeherrschenden Stellung von Patenten offensichtlich ist.
- Folgende Probleme mit DNA-Patenten wurden mässig empfunden: 1. Die Abhängigkeit von Vorgängerpatenten (*crowded art*); 2. Patente, die den Zugang zu Technologien versperren; 3. Schwierigkeiten technologische Gebiete zu erschliessen wegen zu vieler und überlappender Patente.

- Die Teilnehmer der Befragung betrachten ein breit angelegtes Forschungsprivileg und die Begrenzung des Patentschutzes auf spezifische offengelegte Funktionen als Möglichkeiten gegen bestehende Probleme bei DNA-Patenten anzugehen. Sie glauben, dass ein absoluter Schutz von DNA-Patenten die Forschung und weitere Entwicklung von Erfindungen behindern würde. Eine konkrete Offenlegung der Funktion von DNA Patenten würde die Begrenzung von Patentansprüchen ermöglichen.
- Die Teilnehmer äussern Bedenken, dass die Umsetzung eines Forschungsprivilegs durch privatrechtliche Übereinkommen zur Übertragung von Forschungsmaterial (Material Transfer Agreements) umgangen werden könnte.
- Die Umfrageteilnehmer glauben nicht, dass die Einführung einer Neuheitsschonfrist ein geeignetes Mittel bei Problemen mit DNA-Patenten sei.
- Die Teilnehmer geben an, dass es bei Patenten für genetische Testverfahren zu überstarken Marktpositionen kommen kann. Patente können hier die Kosten der Testverfahren erhöhen und es wurden erwähnt dass dies in Einzelfällen dazu führen kann, dass neue Testverfahren nicht entwickelt werden.
- Gegen Probleme bei Patenten auf genetische Testverfahren vorzugehen, erachten die Umfrageteilnehmer ein klinisches Nutzungsprivileg und die Erteilung nicht-exklusiver Lizenzen für patentierte genetische Testverfahren als ein geeignete Massnahmen.

Eine ausführliche Zusammenfassung aller Ergebnisse der Befragung und die Schlussfolgerungen der Studie sind am Ende des Berichts zu finden. Der Bericht ‚Research and Patenting in Biotechnology; A survey in Switzerland' ist elektronisch verfügbar unter http://www.ige.ch/D/jurinfo/j100.htm#2

Résumé

Dans le contexte actuel de notre économie du savoir, on s'attend à ce que la biotechnologie prenne le pas sur les technologies de l'information, créant dans son sillage de nouvelles opportunités pour la société et l'économie au cours du troisième millénaire. Le potentiel qui réside dans les applications biotechnologiques promet d'être, à l'avenir, une source croissante de création de richesse, d'emplois – en grande partie hautement qualifiés – et de nouvelles opportunités d'investissements dans des projets de recherche. La protection de la propriété intellectuelle est ainsi au centre des préoccupations des entreprises biotechnologiques. En effet, les investissements colossaux engloutis par la recherche dans ce secteur et la facilité avec laquelle les résultats obtenus peuvent être copiés les ont particulièrement sensibilisées aux droits de propriété intellectuelle.

La Suisse est l'un des rares pays européens à avoir été très marginalement touché par le récent ralentissement qui a frappé l'industrie biotechnologique. Elle est ainsi en Europe, après la Suède, le pays dans lequel la densité des sociétés biotechnologiques indépendantes par habitant est la plus élevée. La biotechnologie est un marché mondial, et les entreprises suisses pensent en termes de globalité.

Le Conseil fédéral a pris connaissance du rapport relatif aux résultats de la procédure de consultation menée sur la révision partielle du droit suisse des brevets. Avant de le soumettre au Parlement, le Conseil fédéral a demandé, en novembre 2002, au Département fédéral de justice et police d'approfondir certaines questions. Rattaché à ce département, l'Institut Fédéral de la Propriété Intellectuelle (Institut) a alors préparé deux questionnaires afin de mener une enquête auprès d'entreprises privées et d'instituts de recherche actifs dans le secteur biotechnologique, afin de connaître leur position par rapport aux problèmes soulevés dans le domaine de la recherche par les biotechnologie et les brevets sur les inventions biotechnologiques.

L'enquête poursuivait quatre objectifs : premièrement, mieux saisir les enjeux économiques des brevets dits biotechnologiques; deuxièmement, comprendre les problèmes pratiques qui se posent; troisièmement, mettre le doigt sur les lacunes de la législation suisse actuelle; quatrièmement, réunir des connaissances empiriques pour l'actuelle révision partielle de la loi fédérale sur les brevets d'invention. C'est la Directive 98/44/CE de l'Union européenne relative à la protection juridique des inventions biotechnologiques qui a servi de base pour l'enquête.

L'enquête portait plus particulièrement sur les brevets et leur impact sur l'accès à la recherche. Dans quelle mesure et dans quelles circonstances les brevets biotechnologiques limitent-ils la diffusion des connaissances techniques? Afin de répondre à cette question, le présent rapport propose tout d'abord d'esquisser des réglementations possibles des droits de propriété intellectuelle, qui tiennent compte des besoins des entreprises et des instituts de recherche suisses actifs dans le secteur biotechnologique. Parallèlement, il s'agit de reconnaître et d'encourager la recherche, ses résultats et leurs applications. Le présent rapport a également pour but d'encourager la concurrence dans ce secteur et de répondre aux besoins actuels et futurs des utilisateurs de ces inventions et des produits issus de leur application.

En février 2003, l'Institut a envoyé 200 questionnaires à des instituts de recherche et des entreprises de biotechnologie. A la fin mars, 53 questionnaires lui avaient été renvoyés. En août 2003, l'Institut a adressé un second questionnaire aux participants

à l'enquête, dont il a évalué les réponses en septembre. Voici les principales conclusions :

- Les participants à l'enquête confirment que les brevets constituent de fortes incitations aux investissements dans la recherche et le développement d'inventions biotechnologiques.
- Les brevets et les licences sur les inventions biotechnologiques sont considérés comme un puissant moteur de la recherche, des flux de savoir et de la mise sur le marché de nouvelles techniques.
- La Suisse dépose davantage de demandes de brevet par habitant pour protéger des inventions en Europe (OEB), aux Etats-Unis et au Japon que n'importe quel autre pays au monde. Le nombre des brevets biotechnologiques suisses indique qu'il existe des liens étroits entre l'industrie biotechnologique de la Suisse et celle d'autres pays, notamment des Etats-Unis.
- L'industrie biotechnologique suisse est l'une des plus dynamiques et puissantes d'Europe. C'est un secteur avec une forte activité de recherche et de développement, qui enregistre des taux de croissance élevés et présente un fort potentiel d'innovation. De plus, un nombre croissant de demandes de brevet émane de cette industrie. De petites entreprises ayant participé à l'enquête présentent le plus fort potentiel innovateur, mesuré à la densité de brevets par employé travaillant dans la recherche et le développement.
- Appelant de leurs vœux une clarification de la législation régissant les inventions biotechnologiques en Europe et en Suisse (en particulier par rapport à la situation existant aux Etats-Unis), les entreprises actives dans ce secteur sont en faveur de la mise en œuvre, en Suisse, de la directive européenne relative à la protection juridique des inventions biotechnologiques.
- Les brevets, le secret et l'avantage temps jouent un rôle décisif dans la protection des inventions. Les grandes sociétés ainsi que quelques PME ont de ce fait une forte activité brevets.
- Les principales raisons pour lesquelles une entreprise renonce à déposer une demande de brevet sont : 1) les coûts liés à l'obtention d'un titre et 2) l'obligation de divulguer entièrement l'invention.
- Les litiges en matière de brevets jouent un rôle secondaire en Suisse.
- En Suisse, les entreprises utilisent avant tout les avantages traditionnels liés aux brevets. Elles s'en servent ainsi à des fins d'évaluation de l'état de la technique dans un secteur technologique et de protection de leur propre technologie en adoptant une stratégie purement défensive.
- Les participants à l'enquête, en particulier les instituts de recherche, salueraient une réglementation obligatoire en matière de licences dans les cas de monopoles évidents.

- Les participants ont relevé un certain nombre des problèmes de moyenne importance posés par les brevets sur l'ADN : 1) la dépendance aux brevets antérieurs (*crowded art*), 2) existence de brevets bloquant l'accès à des technologies et 3) difficultés à pénétrer dans un secteur technologique en raison du foisonnement de brevets et de chevauchements d'étendues de protection.

- Les participants à l'enquête considèrent que de généreuses dérogations en faveur de la recherche et qu'une limitation de l'étendue de protection des brevets sur l'ADN à l'utilité spécifique exposée dans la demande constitueraient des réponses possibles aux problèmes posés par les brevets dits génétiques. Ils estiment qu'accorder aux brevets sur l'ADN une étendue « absolue » de protection entraverait tant la recherche que les développements futurs. En revanche, préciser l'utilité du gène breveté dans la demande permettrait de limiter les revendications.

- Les participants ont fait part de leur crainte de voir les dérogations accordées à la recherche être contournées par des accords de transfert de matériel biologique.

- Dans l'ensemble, les participants à l'enquête ne pensent pas que l'introduction d'un délai de grâce constituerait un remède efficace aux problèmes posés par les brevets dits génétiques.

- Les participants pensent que le brevetage de méthodes de tests génétiques peut créer de fortes positions monopolistiques. Les brevets sur ces méthodes peuvent en accroître les coûts; dans certains cas, ce renchérissement s'est traduit par un non-développement de nouvelles méthodes.

- Afin de surmonter les problèmes posés par les brevets sur les tests génétiques, les participants à l'enquête estiment qu'il serait efficace de prévoir des exceptions pour les utilisations cliniques et la possibilité, pour les laboratoires cliniques, d'obtenir à des conditions raisonnables des licences non exclusives sur des tests génétiques brevetés.

Un résumé détaillé des résultats de l'enquête et des conclusions auxquelles elle a abouti en termes de réglementations possibles se trouve à la fin du rapport « Research and Patenting in Biotechnology; A Survey in Switzerland », qui peut être téléchargé également à l'adresse http://www.ige.ch/F/jurinfo/j100.htm#2

Table of Contents

1. Introduction

The increasing importance of knowledge in the economy makes issues of access, diffusion and ownership of knowledge more important, in particular under the condition of network effects which characterize much of the knowledge-based economy. Innovation cycles are getting shorter. This means on the one hand that all innovation and innovation-related factors, like human capital, educational skills, research and development, as well as intellectual property rights and their management are rising in importance. Together with the creation of knowledge pools and clusters and the increasing importance of networking, the ownership, quality and protection of knowledge becomes a central issue.

In November 2002, the Swiss Federal Council accepted the summary report on the outcome of the public consulting procedure on the partial revision of the patent law in Switzerland. Before presenting a report to the Parliament, the Federal Council asked the Federal Ministry of Justice and Police to investigate certain questions in more detail. The Swiss Federal Institute of Intellectual Property prepared a questionnaire in order to consult research institutes and private companies in the field of biotechnology on problematic issues of research and patenting in biotechnology.

The survey had four objectives: First, to come to a better understanding of the economic aspects of patenting in the field; second, to achieve an understanding of the concrete practical problems; third, to find out shortcomings within the current Swiss legislation; fourth, to obtain a reliable empirical basis for the ongoing partial revision of the patent law in Switzerland. Finally, the EU directive 98/44/EC on the legal protection of biotechnological inventions in Switzerland served as an important background to the investigation.

While intellectual property rights provide incentives for invention and development, they also reduce the freedom of action for others and can draw activity away from work that is worthwhile but less likely to generate intellectual property rights. One particular focus of the study is the issue of patents and their influence on access to research. To what extent do patents in the field of biotechnology limit the dissemination of technological knowledge, when and under which circumstances? The study considers these questions and further develops the findings from the OECD study ‘Genetic Inventions, Intellectual Property Rights and Licensing Practices’ (OECD 2002), which identifies patents on methods for genetic testing as one of the most problematic areas of patenting. Other studies have found that patenting rarely delays publication significantly, but that it can encourage a climate of secrecy which limits the free flow of ideas and information that are vital for successful science (The Royal Society, 2003).

Based on the empirical data from the survey, this report tries to shed some light on the relationship of patents for biotechnological inventions and their effect on the access possibilities for private companies and research institutes to biotechnological research in Switzerland. The aim of the study is to show possible policy conclusions concerning intellectual property rights, responding to the needs of Swiss biotechnology companies and institutes and taking into account the need to provide recognition and incentives for research, invention and exploitation, to encourage competition and to meet the needs of current and future users of creative work and the resulting products.

Throughout the following investigation it is important to keep in mind that the patent system is a policy instrument to promote innovation and knowledge distribution and that it was introduced to promote wealth. It intends to overcome insufficiencies on markets for technological knowledge and works as a policy tool aiming at creating innovation where it could not appear under free market conditions.

As a consequence intellectual property rights have to be assessed in terms of in how far they fulfil their objective to spur innovation and technology distribution and after all their potential to create wealth. On the one hand patents stimulate innovation and reward people for new and industrially applicable inventions. On the other hand they provide a temporary right to the inventor to prohibit the commercialisation of the new technological knowledge by others than the inventor. Intellectual property rights fulfil their function as an innovation tool as long as the net wealth surplus of both effects is positive.

2. Background

2.1 Patents as an incentive for research and development

Intellectual property rights are supposed to be an important incentive for research and development and they are considered to be a necessary precondition for science and technology to progress. A patent on an invention grants its holder the right to exclude others from commercially exploiting the protected technical invention. There is a trade-off between the disclosure of detailed information by the inventor against the guarantee of limited monopoly awarded by the state.[1] The patent system is designed as an incentive mechanism for the creation of new economically valuable knowledge and as a knowledge-dissemination mechanism to spread this information. In economic literature, intellectual property rights (IPRs) are predominantly understood in terms of their contribution to the 'incentive structure' and less for their role in distributing information about innovation throughout the economy.

The economic argument for IPRs is the market failure in the case of technological knowledge. Technological knowledge is a public good. Its non-excludability (others cannot be excluded from its use) together with its non-rivalry characteristic (the use of technological knowledge by one party does not exclude or limit the use by another party) lead, under free-market conditions, to a reduced incentive for investment in research and development and to an inefficient diffusion. This is the argument for government intervention in the form of establishing an intellectual property rights system. "Patents are designed to create a market for knowledge by assigning property rights to innovators which enable them to overcome the problem of non-excludability while, at the same time, encouraging the maximum diffusion of knowledge by making it public"[2].

In order to achieve the appropriate scope of protection, the right balance between innovation up-rising effects, competition inhibiting effects and positive as well as negative effects on technology distribution must be found. With new technologies and applications of patents different from the initial ones defined by innovation policy, the quality of the patent enters as a new element into the function of the benefits and the costs of the patent system.

2.2 Harmonisation of patent law in Europe

Intellectual property rights systems and their harmonisation are becoming more important, especially since the exchange of goods against goods is replaced by a qualified trade of technologies and by the exchange of technology incorporating goods. Following the concept of national systems of innovation (Lundvall, 1992), technology is not easily transferable across countries but, on the contrary, it is country-specific and based on skills, capabilities and knowledge accumulated over time. Nations differ not only in the quantity of innovation introduced, but also in the methods by which these innovations are adopted and in their industrial landscape. National systems of innovation include intellectual property rights in the public sector.

The remunerative aspects of intellectual property rights have particular significance for biotechnology, since research and development costs are high and the imitation of

[1] Cf. Scherer (1990), p. 623.
2 Geroski, P. (1995), p. 97.

market products is relatively easy. Patents are an important incentive for research and development; they are essential as a bargaining chip for the exchange of technology between companies and for venture capital. Biotechnology companies nowadays operate globally and they appreciate finding similar legal framework conditions on the different markets in which they operate. Different national systems of intellectual property rights, different levels of protection and enforcement can constitute non-tariff trade barriers.

The proposal for a community patent, made in 1989, has still not been adopted, and one of the main problems for European patent protection - apart from the high application and maintenance costs - is the possibility of different interpretations by national laws and national courts, which leads to a high risk of legal heterogeneity within Europe. Thus, there is a need for coherent European regulation for biotechnological inventions, which is the main objective of the directive on the legal protection of biotechnological inventions (COM 98/44/EC). Even though the date for transposition into national law has already passed (July 2000), the directive continues to be subject of fierce debate. Eight member states of the European Union (Austria, Belgium, France, Germany, Italy, Luxembourg, the Netherlands and Sweden) have been taken to the European Court of Justice for their failure to implement the EU directive.

It has to be demonstrated to what extent harmonisation of intellectual property rights direct technological change and if there is a measurable impact on trade, competition and economic growth in general. Historically, intellectual property rights systems developed nationally as part of the national innovation systems. Thus, the question must be asked as to what extent national regulations and institutions are better suited to local needs than international regulations. It is hard to find clear empirical evidence for the benefits of harmonisation. The best indications can probably be provided by the market players themselves. Companies have to be asked about their perceptions of the pros and cons of changing the regulatory framework and about their perceptions of the relevance of certain intellectual property rights policies.

2.3 The context of the study in Switzerland

In December 2001 the Federal Council decided to open the hearing regarding the preliminary draft of the partial revision of the patent law which had been prepared by the Federal Institute of Intellectual Property. The focus of the partial revision was to conform the patent law with EU guidelines on the legal protection of biotechnological inventions in order to provide uniform and clear principles. The impetus came from motion 98.3243 made by Council of State Member Helen Leumann.

The focus of the current patent law revision is the patentability of inventions in biotechnology. The Federal Council launched a public discussion on the controversial issue of patenting biotechnology inventions with a broad consultation on the revision of the patent law at the beginning of 2002. The goal was to achieve a comprehensive overview of the various opinions and issues. This consultation marked the beginning of a public discussion about patenting of biotechnological inventions in Switzerland. The consultation also demonstrated, among other findings, that the discussion on this topic lacks empirical evidence. The Federal Council therefore requested the Swiss Federal Institute of Intellectual Property (under the Ministry of Justice) to analyze certain questions which came up through the opinion-gathering more in detail. Two of the areas to be investigated in detail gave reason for the empirical investigation presented in this study report, namely:

- The impact of patents (in particular gene patents) on biotechnological inventions in basic and applied research;
- The economic (in particular gene patents) implications of patents for biotechnological inventions.

As a consequence the Swiss Federal Institute set up the survey investigation which is the empirical basis for this study report. The two questionnaires on research and patenting had four objectives: First, to come to a better understanding of the economic aspects of patenting in the field; second, to achieve an understanding of the concrete practical problems; third, to find out shortcomings within the current Swiss legislation; fourth, to obtain a reliable empirical basis for the ongoing partial revision of the patent law in Switzerland. Finally, the the EU directive 98/44/EC on the legal protection of biotechnological inventions in Switzerland served as an important background to the investigation. This report will be an essential element of information within the further process of consultation for the partial revision of patent law in Switzerland. A second public consultation is planned for 2004.

2.4 The Swiss biotechnology industry

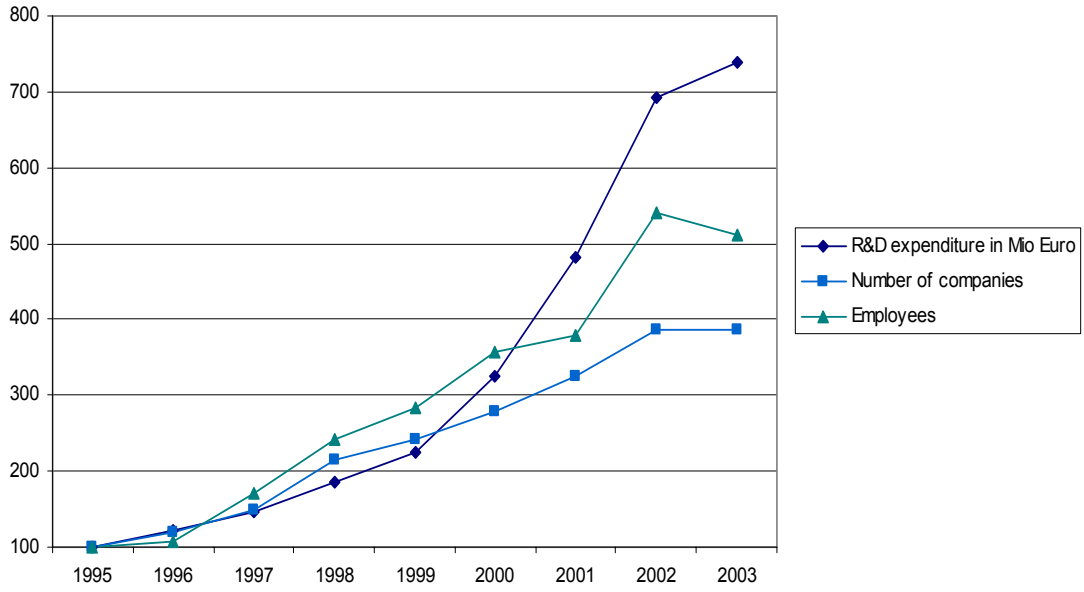
Biotechnology after information technology is generally expected to be the next wave of the knowledge-based economy, creating new opportunities for the society and the economy in the third millennium[3]. Its potential of applications promises to be a growing source of wealth creation in the future, leading to the creation of jobs, many of which will be highly skilled ones and new opportunities for investment in further research. Protection of intellectual property is at the core of the business for biotechnology firms. The high investment costs involved and the ease with which the results can be copied make the biotechnology industry particularly sensitive to the issue of intellectual property.

In comparison with the 1990s, biotechnology companies around the world have come into more difficult times. During the nineties biotechnology experienced sustainable growth rates of several hundred percent (see Figure 1). Only within the last two years this trend has slowly decreased and it has now become clear that the current difficult situation of the world economy has not left biotechnology unaffected. Various biotech indices around the world have fallen tremendously from their peaks in 2000 (Ernst &Young 2003, page 3).

Figure 1 shows that after the strong rise in the biotechnology industry's performance in the 1990s, growth rates for research and development expenditures and company numbers decreased with the number of employees in the industrial decreasing in 2003. This notwithstanding, while biotechnology showed an extremely strong growth in the past, it still shows a very high market potential for the future. Estimates suggest that by the year 2005 the European biotechnology market could be worth over € 100 billion (European Commission 2002c).

[3] There are also voices that doubt that biotechnology will ever approach the pervasiveness of information technology (cf. Arundel 2003).

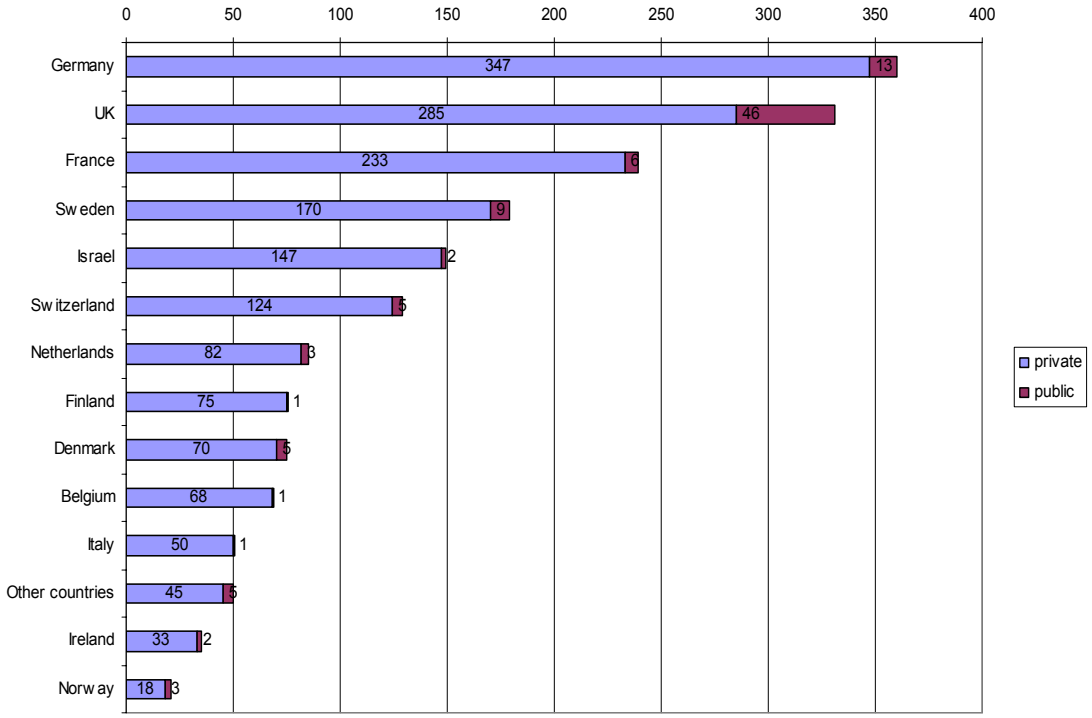
Figure 1 - Development of Europe's Biotechnology industry normalised to 1995



Source: Ernst & Young 1996-2003

In comparison with the United States, the total numbers of European biotechnology companies are small (compare Thumm, 2002, p. 918). The relationship of the market shares within Europe is illustrated by the number of companies in Figure 2. Within Europe, the Swiss biotechnology industry has a leading role.

Figure 2 - Number of European biotechnology companies per country



Source: Ernst & Young 2003

Switzerland is one of the few countries in Europe where the downturn in industrial biotechnology development had almost no effect. Comparably low taxes, political stability, a long tradition in pharma technologies, good universities and a noteworthy banking system are probably some of the success factors of the Swiss biotechnology industry. After Sweden, Switzerland is the country with the second highest number of independent, dedicated biotechnology firms per inhabitant in Europe (Allansdottir et. al, table 4.1). In 2002 there were 129 biotechnology entities in Switzerland, including some of the most innovative biotechnology companies in the world[4]. These 129 entities cover the core of biotechnology in Switzerland together with biotechnology instrumentation and services as well as some biotechnology related companies. With 53 participants, the survey used for this report represents 41% of the Swiss biotechnology industry and is thus a representative sample.

In the 2003 Ernst & Young European Biotechnology report, the Swiss biotechnology industry was presented as a shining example of success in comparison with other European biotechnology industries where most industry activities had declined over the course of the past two years. Swiss companies were shown to be very active with merger and acquisition activities in 2002. As a consequence, the Swiss industry has now the second highest valuation in Europe[5], after the UK industry, despite containing just a fraction of the companies located in the UK and Germany. Probably a lot of these achievements are due to the good industrial basis of the traditional pharmaceutical companies in Switzerland. However, this is by far not the only reason for the Swiss success.

Figure 3 - Swiss survey: distribution of the sample by the year of establishment of the company/institute (n = 48)

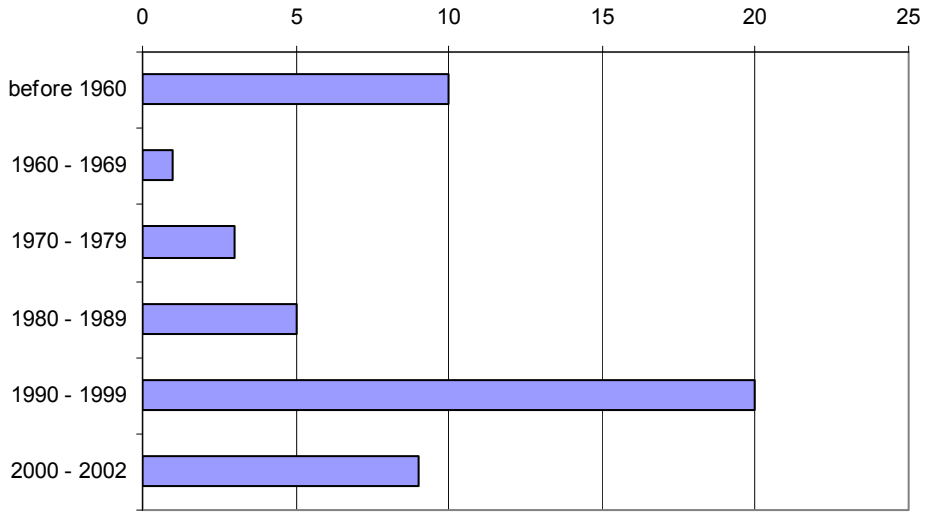


Figure 3 illustrates the distribution of the companies from the sample according to their year of foundation. It is almost impossible to separate the pharma sector from the biotechnology industry in Switzerland. The development of any pharmaceutical product requires the use of biotechnological procedures (cf. SECO 2002, page 66).

[4] Cf. www.technologyreview.com/scorecards/index.asp

[5] Serono is the market leader with a market capital of 6095 €m in 2002, followed by Actelion at position five with 894 €m. Cytos Biotechnology obtained a listing on the Swiss stock exchange after acquiring Askalia Holdings AG.

Most of the companies participating in the survey are fairly new, established between 1990-1999. Another remarkable number of companies were founded within the last three years[6]. It is likely that this high growth rate of new companies will continue in the ongoing decade. As such, Figure 3 shows similar numbers for company growth rates in Switzerland as previously seen in Figure 1 for the total European industry. The separation of traditional pharma companies in the industry and of fairly young companies is characterising the market.

For many of the new companies the success depends on a limited number of individual products which made it from a scientific invention to an innovative product. The strong trend of specialisation of small and young entrepreneurs makes them more dependent on the big companies on the market. Frequently products or processes are out-licensed to big pharmaceutical companies. This goes along with the trend in which small biotech companies make research agreements with big companies where the capital for research is provided in exchange for revenue sharing. These kinds of alliances signify a dominance of small companies by large pharmaceutical firms.

Similarly to the study of McKelvey et.al. (2003) for the Swedish biotechnology industry, the Swiss sample shows three industrial trends: First, a steady flow of new firms (Figures 1 and 3); second, a skewed distribution by size of the companies (many established big companies together with many small new companies); and third, a strong geographical concentration of biotechnology companies (cf. Figure 4).

2.5 Geographical distribution

Typically industries of the knowledge based economy (information technology and biotechnology) follow certain technological regimes and innovation patterns. Under the new regimes of these technologies, adopting a certain division of labour and accomplishing institutional roles is often more important for their economic future than catching up with the next innovation (Ibo van de Poel page 66). Geography as an element of collaboration and integration is an important economic opportunity within technological regimes.

[6] According to a presentation of the Swiss Life Sciences Database www.swisslifesciences.com at the First Tuesday Meeting in Zürich, March 11th 2003, 2000 was in this respect so far the most active year in Switzerland with 21 biotechnology firm foundations.

Figure 4 - Swiss survey: geographical distribution of the Swiss biotechnology companies/institutes providing responses to questionnaires, one square represents one company

Figure 4 shows the geographical distribution of the companies / institutes which participated in the survey (one square represents one company). Major centres of biotechnology conglomerations are the regions of Basel, Zürich and the Lake of Geneva / Région Lémanique (Geneva, Lausanne). Smaller centres are Fribourg and Bern. It appears that the Swiss biotechnology industry concentrates around the economic centres as well as around the most important universities in Switzerland.

Three factors may be decisive for the collocation of new industries: the disposal of human capital, the availability of venture capital and the proximity of other biotechnology firms. It would be interesting to examine the relationship of these three factors in terms of the location of biotechnology firms in Switzerland. Various elements would have to be taken into consideration. One would expect that regions with a larger population of biotech and venture capital firms are predisposed to attract further biotech companies, together with specialized service providers such as biotechnology consultancies and patent law firms.

Findings from other studies have shown that, especially for start-ups, close proximity to dense clusters of structurally equivalent high-technology firms can also have a negative influence on business performance. According to Stuart and Sorenson (2003), biotechnology start-up companies favour locations where an extensive technical workforce is available without intensive local competition from nearby biotech firms. The highest danger for these companies is that well-funded competitors can recruit top talents away. The authors further found that even though the proximity of universities with biotech-related sciences is important for knowledge transfer to companies, the exchange of labour from universities to companies might be restricted since university staff finds it often more convenient to collaborate as an external consultant or to join the scientific advisory board of a company than to create their own company.

With respect to business performance, geographical co-location is less important for firm-to-firm deals or for university-to-university co-authored papers than for firm to university deals (McKelvey et al. 2003, page 499). These findings suggest that apart from the three major geographical foci of biotechnology industry in Switzerland (Zürich, Basel, Geneva/Lausanne), there is a high potential for new biotechnology foundations in all other university connected regions of Switzerland (Lugano, Bern, Luzern, Neuchâtel, Fribourg, St. Gallen).

Although Switzerland has benefited from the recent boom and the capacities of biotechnology excellence in science, it is still essential that it maintains a good capacity for transferring knowledge into new products, processes and services. The development of new capacities involves the encouragement of the entire research and innovation process to attract and train researchers. It helps to attract investment and resources and to provide a balanced and responsible legal, regulatory and policy framework. As the patent system is an important element of building capacity for biotechnological innovations, the European biotechnology Directive on the legal protection of biotechnological inventions promises to improve the legal certainty for Swiss companies in coherence with a Europe-wide framework.

3. Methodology of the Survey

The survey 'Research and Patenting in Biotechnology, A survey in Switzerland' was developed by the Swiss Federal Institute of Intellectual Property. The first questionnaire (Annex 25) covered four main parts: Part A, general questions, Part B, intellectual property rights management, Part C, DNA patents, Part D, genetic testing. In February 2003, the Swiss Federal Institute of Intellectual Property sent out 200 questionnaires[7] to research institutes and to private companies accompanied by a letter underlining the importance of the survey in the context of the ongoing patent law revision in Switzerland. In order to match as much the Swiss biotechnology sector as possible, data where taken from the yearbook of the Swiss Biotechnology Federation as well as from the Swiss Life Sciences Database (http://www.swisslifesciences.ch/page/index.html).

All companies had the possibility to either complete a printed version of the questionnaire and to return it via mail, or to send back an electronic reply with a questionnaire to be taken from the internet (http://www.ige.ch/jurinfo/biotechnology-survey.htm). By the end of February 2003 reminders were sent to all companies which until then had not responded to the questionnaire. Many of the companies supposedly under the heading of ´Swiss Biotechnology´ turned out to be pure trading or consulting companies without a research and development division. Once identified, these companies were not taken into further consideration for the survey.

By the end of March 2003, 53 completed questionnaires had been returned, which corresponds to a good response rate of 26%. The results from the evaluation of this first questionnaire made clear that for a number of issues there was further need of clarification. A second, more specific questionnaire was designed to retrieve in-depth knowledge on the points, which needed further clarification. In particular information was requested with respect to the judiciary patent system in Switzerland, the issue of secrecy versus patenting and its remedies, the European biotechnology directive, the introduction of a grace period, the implementation of a research exemption in Switzerland and issues of licensing. The second questionnaire (see annex 26) was mailed in August to all the participants who had returned the first questionnaire and was evaluated in September 2003. From the earlier 53 participants, 33 questionnaires were returned and eventually evaluated. The second return rate, although lower, is still within a representative range.

3.1 Formulation of the questions

The formulation of the questions directly influences the quality of the information obtained. Badly formulated questions can lead to wrong answers or non-response. Following the empirical 'good practice' criteria for the formulation of questions, they should be simple, unambiguous and neutral. A systematic revision of the formulation of the questions by a number of competent persons tried to assure that these criteria were met.

In order to make the responses suitable for quantitative analyses, scales that allow assigning quantities to the qualitative statements had to be constructed. The questions were designed according to the following criteria:

[7] The complete questionnaires can be found in Annex 25 and 26.

- Measure, as precise and direct as possible, the corresponding factor;
- Support qualitative judgements when evaluating qualitative factors;
- Cover the whole scope of the possible answers;
- Be easy to understand and respond to (this includes the application of as few different scales as possible);
- Make sure that a correct quantitative division can be applied to the qualitative (semantic) division of the scale in the analysis.

From these criteria emerges a typical dilemma in questionnaire design. On the one hand, the methods of analysis to be applied require quantitative data. On the other hand, most of the factors concern qualitative issues that are difficult to translate into quantities. The present questionnaire tried to solve this dilemma by using three different kinds of questions.

First, open questions where the participants were asked to give their opinion and provide qualitative data, such as:

- Which patenting and licensing strategies and tactics have been commercially successful in your company? Please explain briefly:

Second, questions where the answers are discrete quantitative data, like:

- How many patent applications have been filed by your company/institute in the field of biotechnology during 2000-2002?

The third kind of question used an ordinal measurement scale for the answers, where the person answering is confronted with five options and where the owner expresses accordingly an opinion. This kind of representation is used in order to express the degree of importance, of satisfaction, of agreement etc. as with the following question:

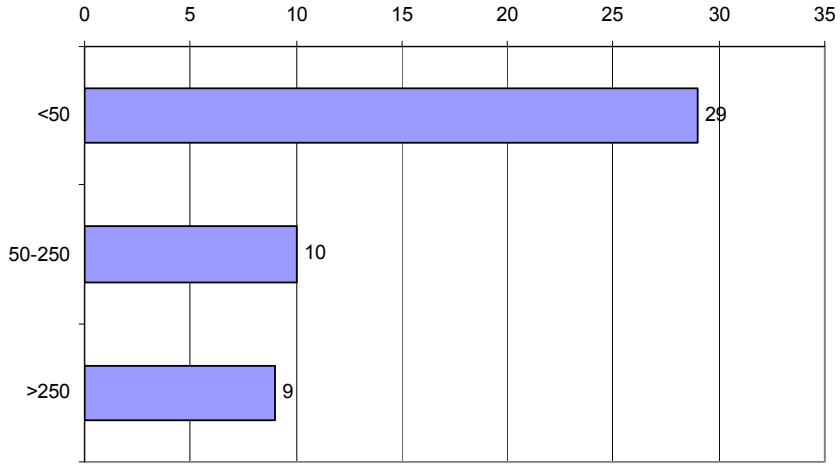
- How important are patents for your company/institute in the context of:

	not Important	modestly	medium	important	very important
The acquisition of venture capital?	☐	☐	☐	☐	☐
Mergers with other companies?	☐	☐	☐	☐	☐
Co-operations with other companies?	☐	☐	☐	☐	☐
	1	2	3	4	5

The evaluation connects the answers with an ordinal scale from one to five, where one stands for a low degree and five for the highest degree. An average higher than three stands for a strongly positive answer, whereas an average value of two and lower can be interpreted as a disagreement. Criteria of analysis were the different behaviour of private companies on the one side and public research institutes on the other side, as well as the differences in performance between small, medium and big enterprises.

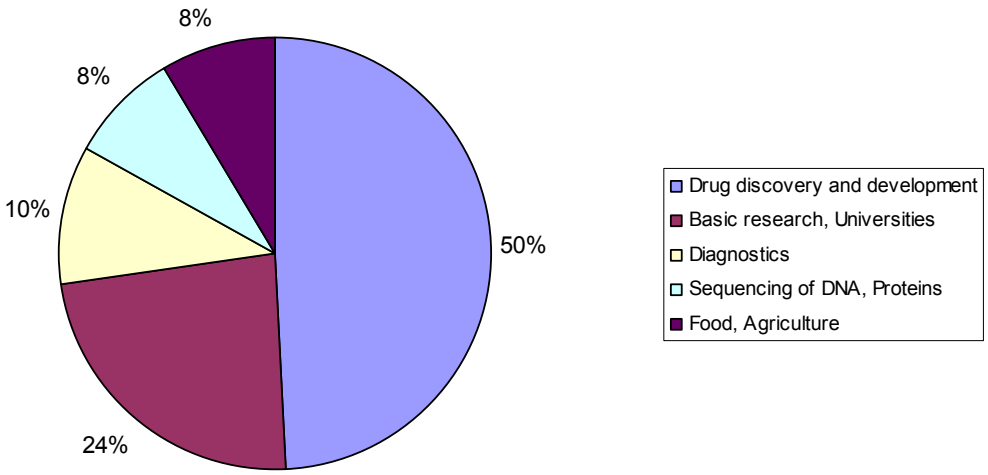
3.2 The sample composition

Figure 5 - Swiss survey: distribution of the sample by the number of employees



The report distinguishes between small companies with less than 50 employees, medium-sized companies with 50 to 250 employees, and big companies with more than 250 employees. Some 42 private companies and 11 research institutes completed the Swiss first questionnaire (annex 2). The highest portion (29) of respondents was small enterprises. The rest of the sample is equally represented by medium-sized companies, and by big companies (see Figure 5). Respondents were asked to indicate their core field of activity. The biggest percentage (50%) of the companies/institutes works in the field of drug discovery and development. Another quarter is involved in basic research while the rest is equally distributed among the fields of diagnostics, sequencing of DNA and proteins, and food and agriculture (Figure 6).

Figure 6 - Swiss survey: distribution of the sample by the core business



With regard to the follow-up questionnaire, 33 replies were registered from 25 companies and 6 research institutes. Eleven small companies, 10 companies with more than 50 employees and 5 companies with more than 250 employees participated in the second questionnaire. Given the 129 biotechnology entities indicated by Ernst & Young in Switzerland (see Figure 2) this is still a representative size for the analysis of the questions.

4. Patenting in Switzerland

4.1 The 'Pro-Patent-Era'

The last decade has been described by some commentators as a 'Pro Patent Era', an era with a vehement increase of general patenting activity in many industrial sectors (European Commission 1999, page 14). The underlying reason could reflect a fundamental increase in inventive activity. It could also mean, however, that patents are now used for different reasons than their traditional appropriation function, generally known as 'strategic patenting' and that this leads to a strong increase in the demand for patenting.

Though the intellectual property rights system has existed for a long time, it has, with the exception of the chemical and pharmaceutical sector, not generally been considered to be an important element of the economic system as a whole. However, in the 1980s, a 'pro-patent' era emerged for a number of reasons. The general recognition of the transition towards a knowledge economy and technological competition had focused attention on intellectual property issues, while the competitive success of Japanese companies in particular drew attention to patents and the difficulties which US companies had in protecting their R&D investments.

As a consequence, the patent system and its exploitation became significantly strengthened in the USA by a variety of measures. Astonishingly the increase in patenting was experienced broadly across the spectrum of technologies, not just the biotechnology and software industry, and was not only driven by the big companies in the market, but included a reasonable share of small companies.

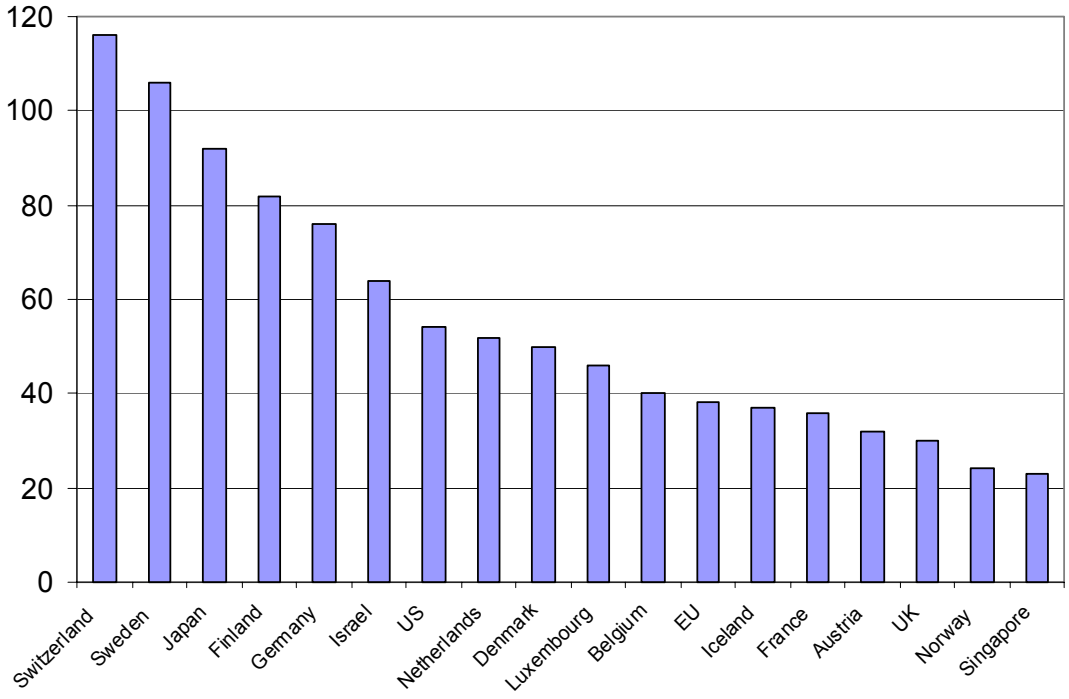
According to Kortum & Lerner (1999), the main reason for the pro-patenting era is a change in the management of innovation, involving a shift towards more applied activities. This is accompanied by firms being conscious of the importance of intellectual property rights and innovation management. In Germany, there was a 95% growth in the 1990s, combined with a patent intensity jump and a trend towards stronger internationalisation. Most industrial sectors showed a drastic increase of EPO/PCT applications in 1995 (Blind, et al. 2003). The trend of growing patenting activity in the past which has been confirmed by a variety of surveys is expected to continue in the near future.

In a recent OECD survey, 75 % of the firms reported, that they patent inventions today which they would not have thought to patent ten years ago (OECD 2003). The survey also shows that the number of patents per invention has increased over the last decade and that an increase in the bargaining power of companies and higher product market competition are the most important factors underlying this trend in patenting.

What is the position of Switzerland in this rising patenting trend? For a national comparison of patenting performance, triad patents have been shown to be fairly good indicators. Triadic patent families relate to those patent applications filed with the European Patent Office, the Japanese Patent Office and US Patent and Trademark Office. Most of these applications are coming from the United States, Japan and Germany (cf. OECD 2003a page 13). Switzerland is eighth in triadic patent families. For a small country, this stands for a high innovative potential with an international scope. This strong position of Switzerland with respect to patenting

becomes even clearer when looking at the triadic patent families per million inhabitants (Figure 7). Switzerland, together with Sweden, is the leading country, with more than 100 patent families per million inhabitants.

Figure 7 - Number of triadic patent families per million population according to the residence of the inventors, for priority year 1999.



Source: OECD 2003a

4.2 Biotechnology patents in Switzerland

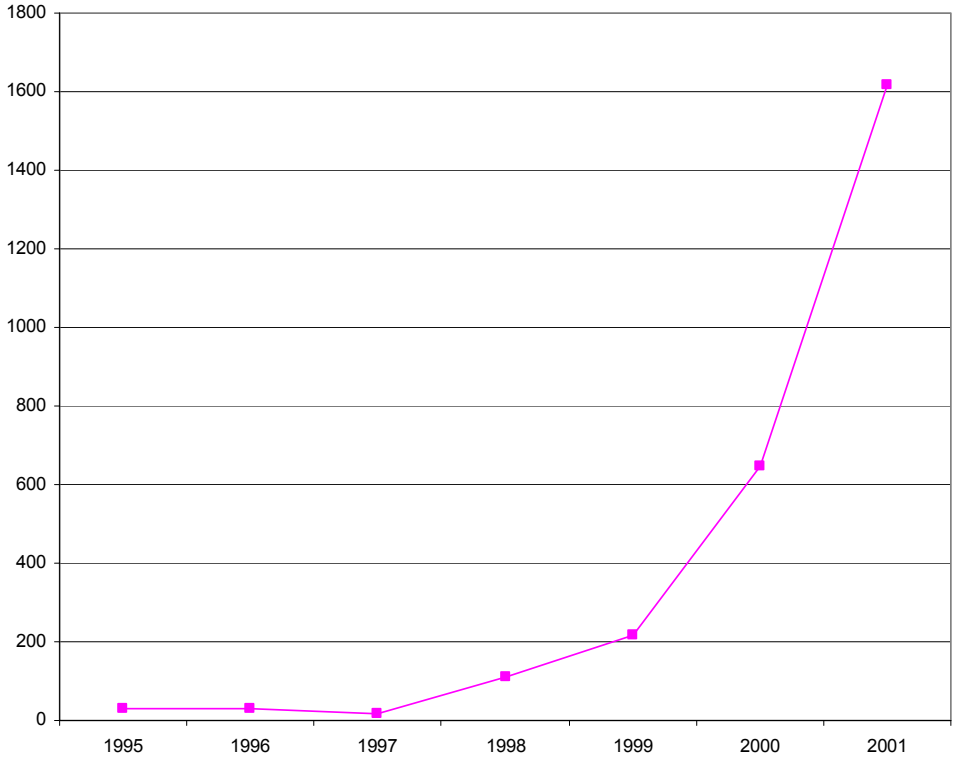
It is important to keep in mind that biotechnological inventions require high capital investment, long development cycles and comprehensive regulatory approval. Effective patent protection is a crucial incentive to investments in research and development, especially for biotechnology inventions.

We have already shown that the Swiss biotechnology industry is in a strong position in comparison with the biotechnology industries of other European countries. To achieve a representative picture of patenting activities in this sector it is useful to look at patent applications for genetic engineering[8]. They represent the majority of patent applications in the field of biotechnology[9]. European patents in genetic engineering are strongly increasing. The numbers for Switzerland, shown in Figure 8, are representative for the overall industry trend in Europe. The strong increase of patent applications in Figure 8 shows the growth of the biotechnological industry as such.

[8] IPC class C12N: Micro-organisms or enzymes: compositions thereof; propagating, perserving, or maintaining micro-organisms; mutation or genetic engineering; culture media.

[9] Biotechnology patents comprise the following IPC classes: C07G; C12M,N,P,Q,R,S.

Figure 8 - Genetic engineering (IPC class C12N) Biotechnology patent applications in Switzerland via PCT with designation of Switzerland.



Source: Derwent World Patents Index

The patent applications in Figure 8 are patent designations for Switzerland. One can assume that approximately 35% of these applications originate from the United States and about 10 % from Japan (cf. Thumm, 2001, page 260), the rest are of European origin. To illustrate the comparative dimensions of the European and US American Market: Europe applies for about one-tenth of the biotechnology patents in the United States (cf. Thumm, 2001, Figure 2). The Swiss patent applications in Figure 8 are almost entirely designations with a foreign priority application. This does not mean that Swiss companies do not file patents. It means considering that the biotechnology market is an international market, that Swiss companies file their priority applications elsewhere than in Switzerland.

Swiss biotechnology companies think globally and the Swiss market, even though of relevance, is comparatively small in size. In most cases of valid patents, a European application follows automatically. One reason for this result is that applications per country are counted according to the residence of the inventors. The Swiss biotechnology industry is international and there are many foreign employees working in Switzerland, as well as many Swiss who work outside of the country for their companies. On the one hand, with over 20 percent Switzerland is a country with many domestic inventions owned by foreigners (OECD 2003a, page 28) which, in a way, is typical for a small country. On the other hand, Switzerland, with over 40 percent, is one of the countries with the highest percentage of EPO applications for inventions invented abroad (OECD 2003a, page 29). This shows the international dimension of the Swiss biotechnology industry.

Patents are frequently used as an economic indicator. The amount of patenting of a country or company can be interpreted as a measure of innovative capacity. This concept, frequently used in the field of innovation policy, is however, not without shortcomings (cf. Griliches, 1990 and Thumm, 2000, page 39 ff). Some Swiss companies are among the leading companies in the world with respect to the number of patents per company and also with respect to the number of patents being cited per company (in particular Hoffmann-LaRoche and Novartis are very patent intensive companies. Cf. the CHI/MIT study and the TR Patent Scoreboard 2003, www.technologyreview.com/scorecards/index.asp).

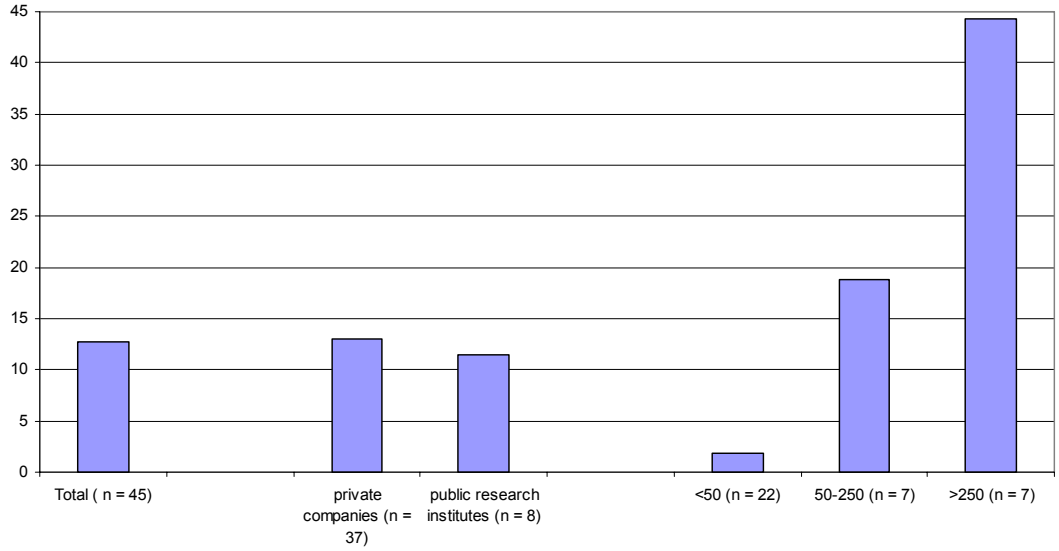
According to another study (Allansdottir et al., page 7), Switzerland is the eighth country with EPO biotechnology applications during the years 1990 and 1997. This study also makes a country comparison on the basis of a Revealed Technological Advantage (RTA) index (Allansdottir, page 12 and Table 2.3). The RTA is a country's share of all patenting in a given technology/sector relative to the share of patents in a specific industry over all technologies/sectors. The revealed technological advantage represents a country's relative innovative specialisation in a certain technological field. The index makes clear that the patent portfolio of biotechnology, materials, organic chemistry, pharmaceuticals and polymers for Switzerland is strongly dominated by patents from the organic chemistry sector, and it shows that the Swiss pharmaceutical industry is predominating the Swiss life sciences scene. It does not, however, mean that biotechnology patents are not of importance in Switzerland, but that biotechnology patents in Switzerland are by far outnumbered by organic chemistry patents.

Swiss assignees invent almost half of their biotechnology patents in the United States. Between 1987 and 1996 only 31% of biotechnology patents with a Swiss assignee were invented in Switzerland. Some 48% of these patents were filed in the United States, another 18% in other European countries (Allansdottir et al., Table 2.5). This finding confirms the close link between the Swiss multinational pharmaceutical and biotechnology companies in the United States and other European countries.

4.3 The patenting activity in the Swiss sample

Survey participants were asked how many patent applications their company or institute had filed in the field of biotechnology during the period 2000 to 2002. The average number was relatively low with 12.8 patent applications per company for the whole period. The number of patent applications within the sample, however, rises with the firm size. Figure 9 confirms that most patent applications in the field of biotechnology belong to big companies:

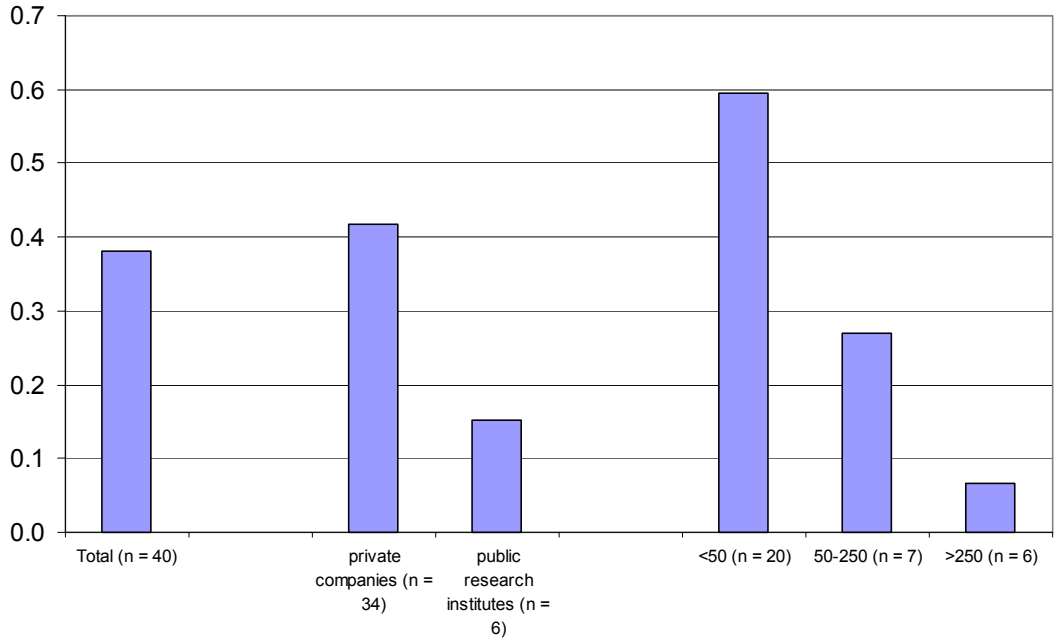
Figure 9 - Swiss survey: number of biotechnology patent applications filed per entity



Most small companies have few patent applications in the field of biotechnology, although there are some very successful ones with 27-50 patent applications in this period. It was shown earlier that although small companies do not apply for many patents, when it comes to certain motives like the acquisition of venture capital they have a very strong interest. Small companies are also more innovative in terms of patent applications per employee in research and development (see Figure 10). The situation is slightly different with DNA patents: most of the DNA patents are coming from research institutes (Annex 13). Probably DNA research is more strongly linked to basic research than general biotechnology.

On average, about 50% of the employees in the companies work in research and development. With small companies, this percentage is even higher. This illustrates the extremely strong research and development orientation of the biotechnology industry in general. Correspondingly, research and development expenditures are very high and on average 40% of the total turnover of the companies (Annex 4). Research institutes and small companies invest almost 50% of their total turnover into research and development.

Figure 10 - Swiss survey: number of patent files per employee in R&D



It is interesting to look at the number of patent applications per employee in research and development (patent intensity, Figure 10). The patent intensity is twice as high for small companies than for big ones. These numbers are only relative numbers and do not explain much about the total number of patent applications. Big companies apply for far more patents than small entities. Figure 10 illustrates that the potential per employee for patentable inventions is actually the highest with small firms. The relationship between the number of biotechnology patent applications and the year of establishment of the company/institute is of interest.

Figure 11 - Swiss survey: relationship between the age of the company/institute and the number of biotechnology patent applications filed

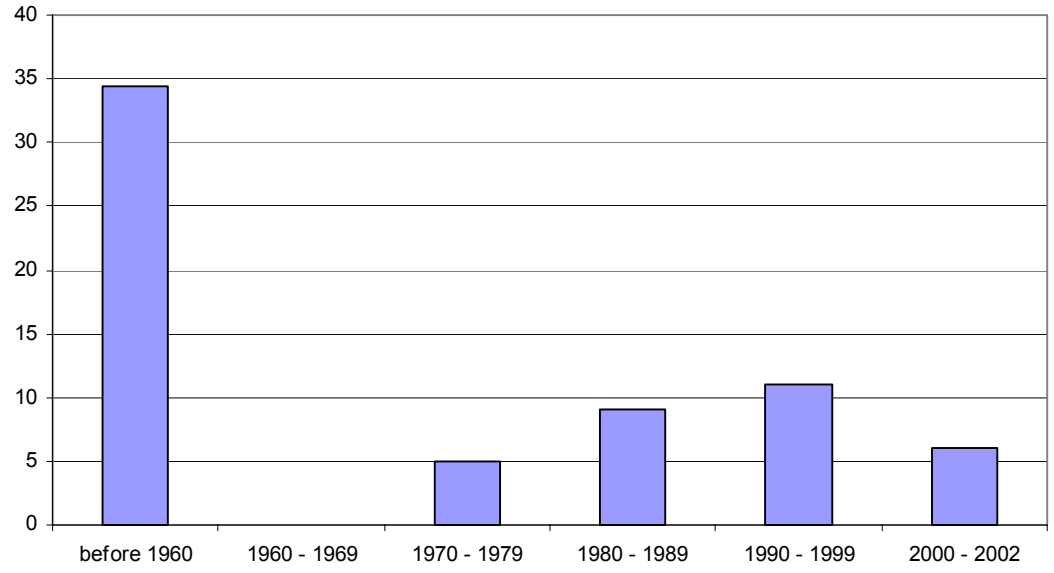


Figure 11 shows that companies/institutes founded before 1960 show, on average, by far the highest numbers of patent applications. These companies are the big pharmaceutical companies and long-established research institutes and universities. In the last decades younger companies/institutes applied for more patents than older entities. Obviously younger firms are more dynamic with respect to patenting. It would require more in-depth research to see to what extent younger enterprises are more innovative and to what degree they are less reluctant towards the use of the patent system.

All survey participants were asked which countries are the 10 most important for their company/institute when applying for patent protection and to list them in the order of the importance. Figure 12 shows the ranking:

Figure 12 - Swiss survey: importance of countries for patents to apply for (sum of ranked positions, n = 45)

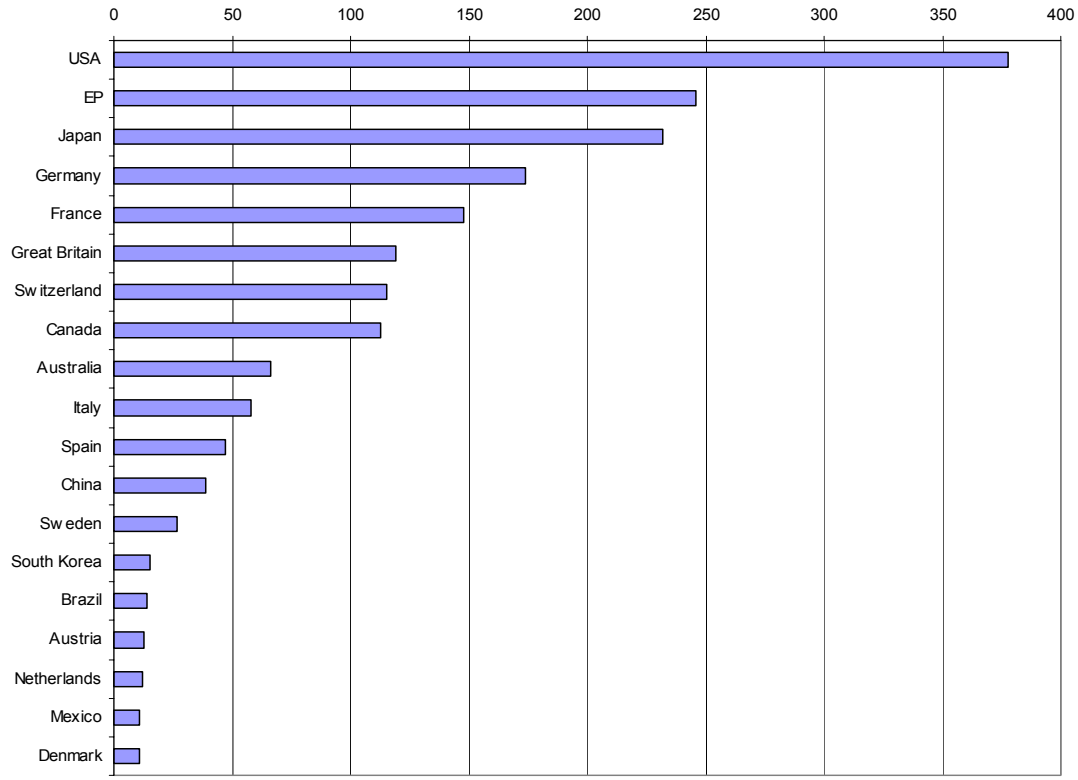


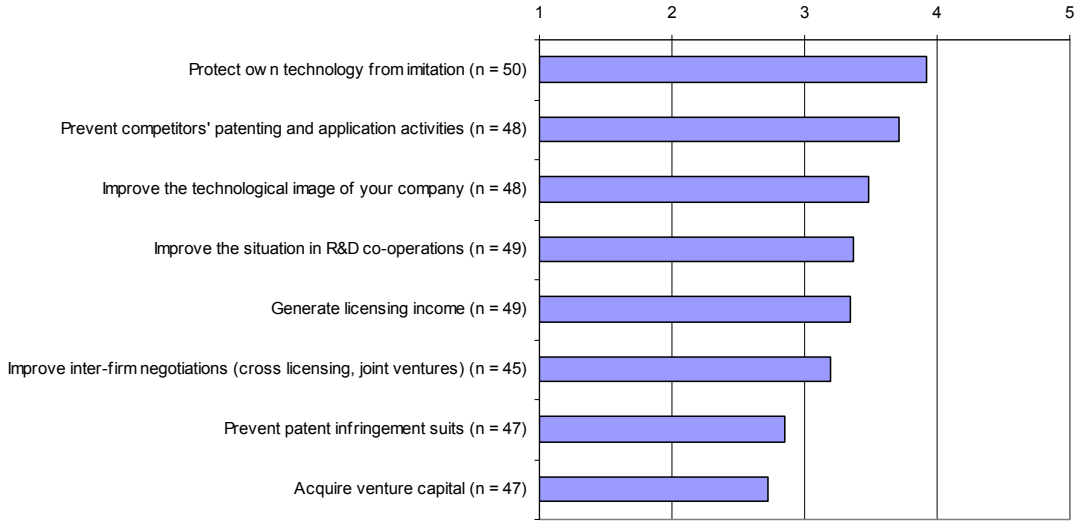
Figure shows clearly that biotechnology is a global market. Swiss companies think globally or, as has been discussed previously, are globally interlinked. The US market is the most important and largest for biotechnological products in the world, followed by the European and Japanese market. Some European countries where competition is strong, like Germany and Great Britain, also received a high ranking. The national Swiss market is important but in the global perspective of biotechnology companies it is only one among many national markets.

5. Management of Patents

5.1 Patenting motives

There are many different motivations for applying a patent. Figure 13 lists a variety of them. It shows that the classical, defensive motive of protecting one's technology from imitation (25 participants gave it the highest rank) and preventing competitors' patenting and application activities are the most important motives for the Swiss sample. Surprisingly, the technological image is an important reason for applying for patent protection for small companies. The survey of Blind et al. (2003) confirms that patents are important for the technological image of a company. In comparison to other studies (Blind and Thumm, 2003) it is less important to improve the situation in research and development co-operations with patents and to generate licensing income in general. The generation of licensing income is very important only for research institutes (Annex 21). The big efforts to raise awareness about patenting and licensing at public research institutes over the past years could be one reason for this. A higher need to receive external funding during the past years could be another reason.

Figure 13 - Swiss survey; importance of motives to apply for a patent (1=very low, 5=very high)

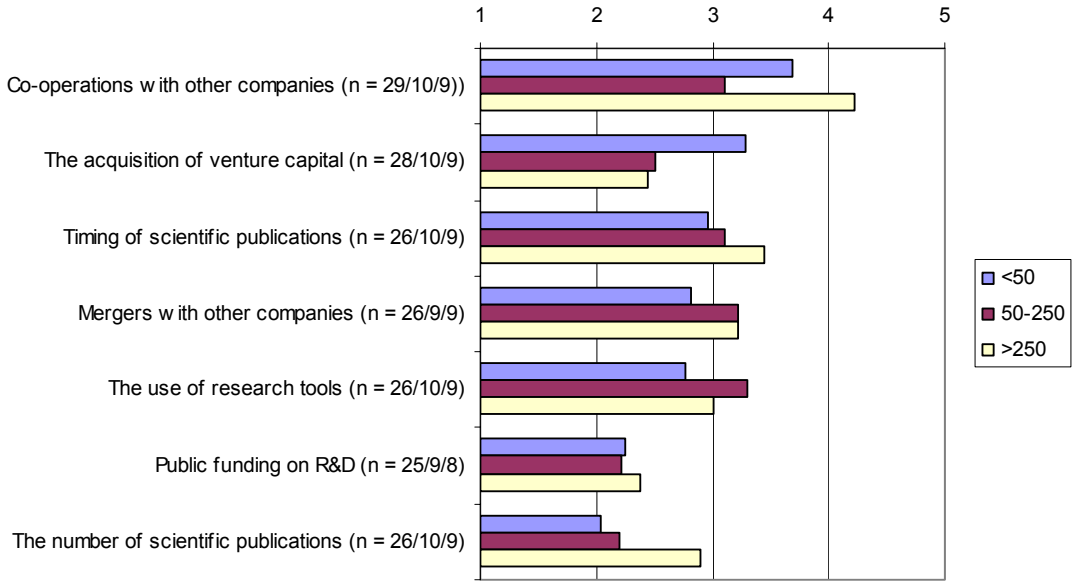


For big companies, apart of the acquisition of venture capital, all patenting motives are important. Only small companies consider the acquisition of venture capital to be a very important reason for applying for patent protection. Smaller companies also rate the generation of licensing income as being of highest importance. The motivation to prevent competitors increases with the firm size.

5.2 Importance of patents

The participants were asked to rate the importance of patents for their company/institute in different contexts. The results to these questions are shown in Figure 14:

Figure 14 - Swiss survey: Importance of patents in the context of different fields, (1=very low, 5=very high) only companies



Overall, for most participants in the survey, patents are very important for co-operations with other companies and for timing their scientific publications, but less important for funding research and development and for the number of scientific publications. Companies place higher value on patents in the context of co-operations and mergers with other companies than research institutes (Annex 5) while research institutes place more value than companies on patents for the financing of research and development. For big companies, patents are more important, when it comes to co-operations or mergers with other companies, whereas small companies consider patents to be highly important for the acquisition of venture capital[10]. A closer look at the ratings of patents for the acquisition of venture capital and mergers shows a u-shaped structure for small companies: some small companies do not consider patents to be important at all in this context (answer 'not important'), but more small companies consider patents to be very important. This u-shaped distribution of answers applies to various questions in the survey for the small companies.

Patents in the context of mergers with other companies should receive special attention in Switzerland. The reason for this is that in 2002 the biggest biotech to biotech acquisition in Europe was the Swiss vaccine producer Berna Biotech's takeover of the Dutch Rhein Biotech. Other Swiss companies, like Modex Therapeutics Ltd and Serono have recently been very successful with the acquisition of other companies (Ernst&Young 2003).

5.3 Patent litigation

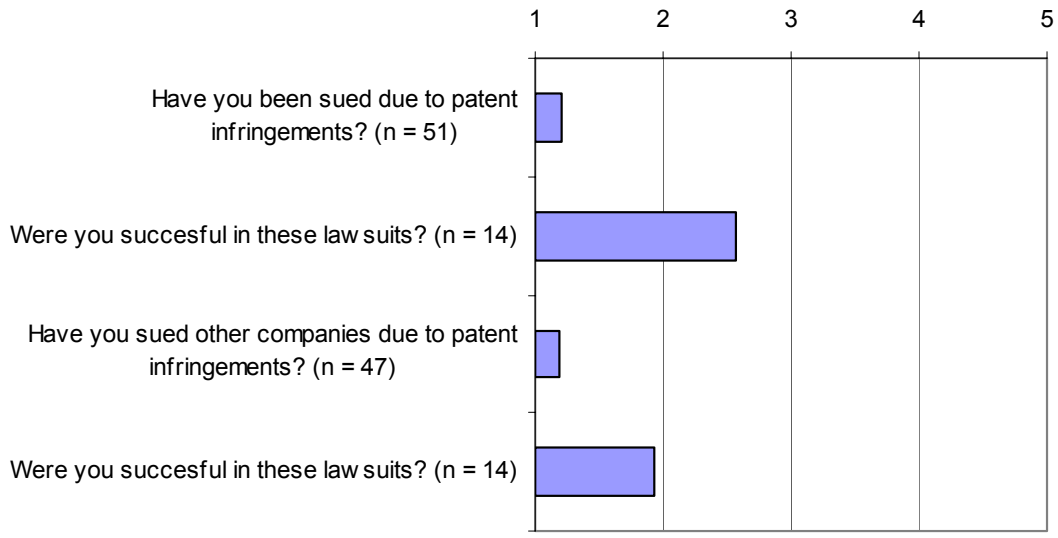
The rise in patenting over the last decade would suggest an increase in litigation and patent infringement. In a recent OECD survey, 70% of the participating firms report

[10] Which does not mean that venture capital is not important to big companies. Cytos e.g., one of the leading Swiss biotechnology companies was number six of the European top venture funding companies in Europe (Ernst & Young, 2003, page 12).

growing involvement in patent infringement suits (OECD 2003). Another study, however, finds that the litigation rate per patent has not risen, that there is a great variation across patents and patent owners in litigation rate (Schankerman, 2003). The same study reveals that in the United States, the number of patent suits has grown tenfold over the last two decades, but that the same is true for the number of patents. In terms of policy it is interesting that the study shows that valuable patents are more likely to be litigated and that small firms and individuals are more likely to sue than large companies. The reason for the latter finding could be a psychological element that individuals and small firms feel that their few patents are of high personal value. As a consequence, they are more likely to go to court to defend their patent rights. In this sense it is both the objective and the psychological value of a patent that determine the likelihood of a patent being brought to court.

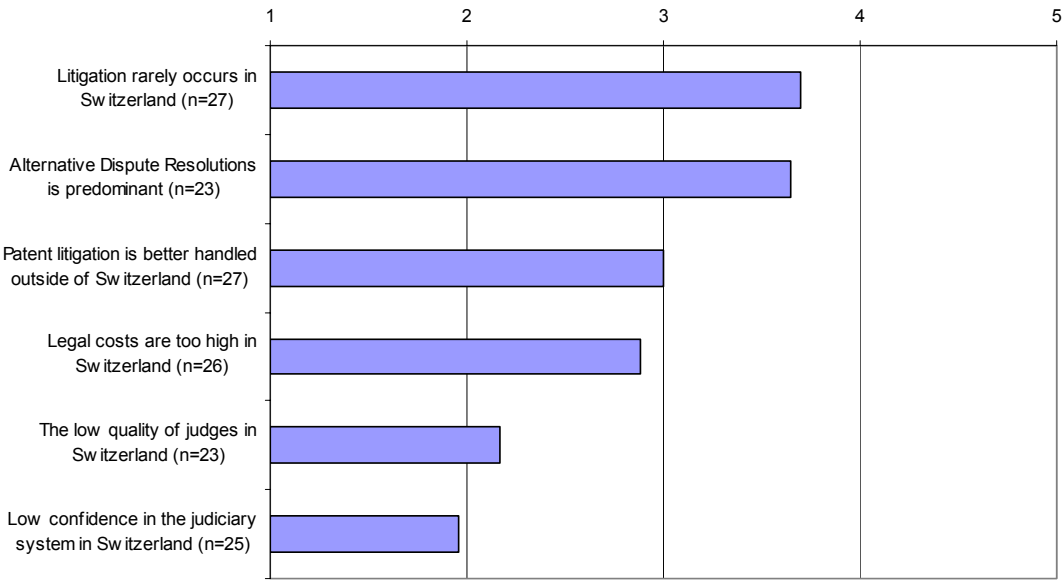
Figure 15 indicates that patent law suits have obviously not been a problem in Switzerland. Companies have not been sued, nor have they sued other companies. Large companies possess generally a much higher in-house expertise with patenting than small companies (Annex 6). Consequently, in the few legal cases which were brought before a court, larger companies were more successfully defending their rights than smaller companies (Annex 7). Even though some small companies have an excellent expertise with patenting.

Figure 15 - Swiss survey: legal issues I (1=never, 5=very often)



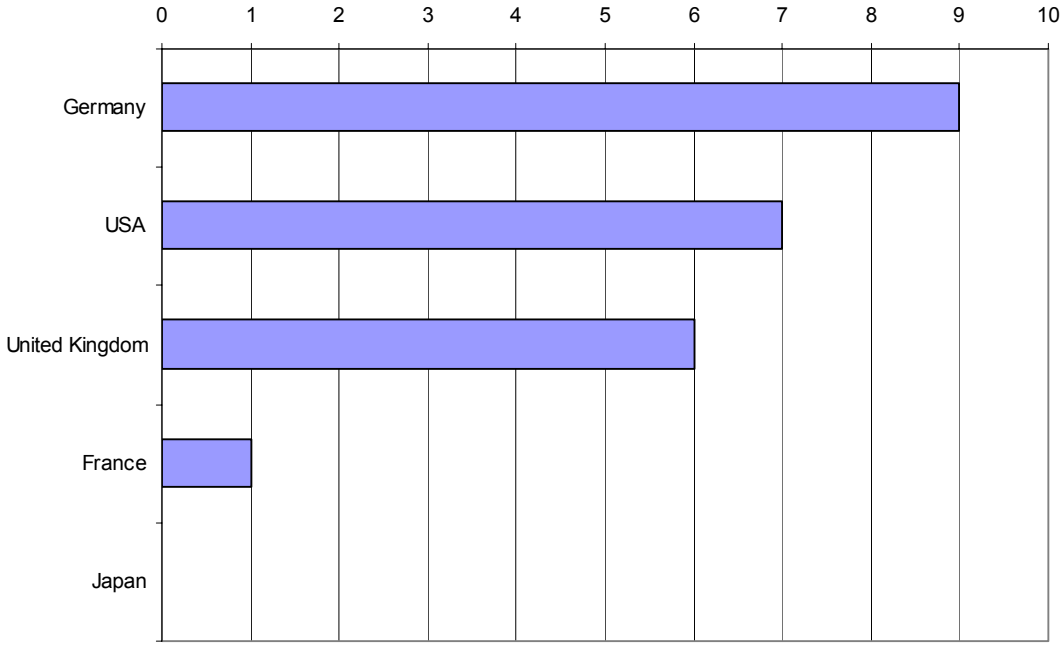
Relative to the low numbers of lawsuits, infringement costs have not been a problem for most of the participants in the survey. Only big companies, naturally more involved in lawsuits, indicated that legal costs were high (Annex 8). Big companies also indicated that they were very successful with their law suits. This taps on the main concern regarding infringement, namely that the patent system gives large firms an advantage over small firms. The low level of litigation, indicated in the first questionnaire, gave reason to inquire in more depth why it is rather exceptional for firms in Switzerland to go to court for patent litigation. In the follow-up questionnaire participants from the first questionnaire were asked their opinion for the reasons for the low level of patent litigation in Switzerland. It is indeed astonishing that litigation in Switzerland rarely occurs, for whatever reason, and that alternative dispute settlement is predominant (see Figure 16).

Figure 16 - Swiss survey: Reasons for the low number of patent litigations in Switzerland (1=no agreement; 5=total agreement)



The second survey showed that the low level of litigation is not a matter of low quality of the judges in Switzerland, nor is it an expression of lack of confidence in the judiciary system in Switzerland. Both, companies and research institutes confirmed this (Annex 9). Research institutes and small companies in the sample find that the legal costs in Switzerland are too high. Companies with more than 250 employees believe that litigation rarely occurs in Switzerland and at the same time they think that patent litigation is better handled outside of Switzerland (Annex 10). Today, more than 60 % of the patent cases are decided by the four commercial courts, specialised in intellectual property. The rest are, however, decided by courts having no or hardly any experience in patent law (Luginbuehl, 2003). Those companies believing that patent litigation is better handled outside of Switzerland were further requested to indicate where they prefer to litigate instead. This question offered multiple answers (see Figure 17). The cantonal court system in Switzerland was mentioned as a disadvantage in this respect by some big companies.

Figure 17 - Swiss survey: 'If you believe that litigation is better handled outside of Switzerland, where do you prefer to litigate?' (counted answers, multiple answers possible)



Few answers were received to this question. Thus one has to be careful with the interpretation of Figure 17. Germany, is a close neighbour and one of the world`s leading patenting countries in terms of total numbers of patent applications with a fairly established and respected patent court system. It is well known that many companies prefer to litigate in Germany if they can choose from different EPC contracting states. The German system was mentioned as having the advantage that, during infringement trial it does not question the validity of the patent. This would help to finish litigation sooner.

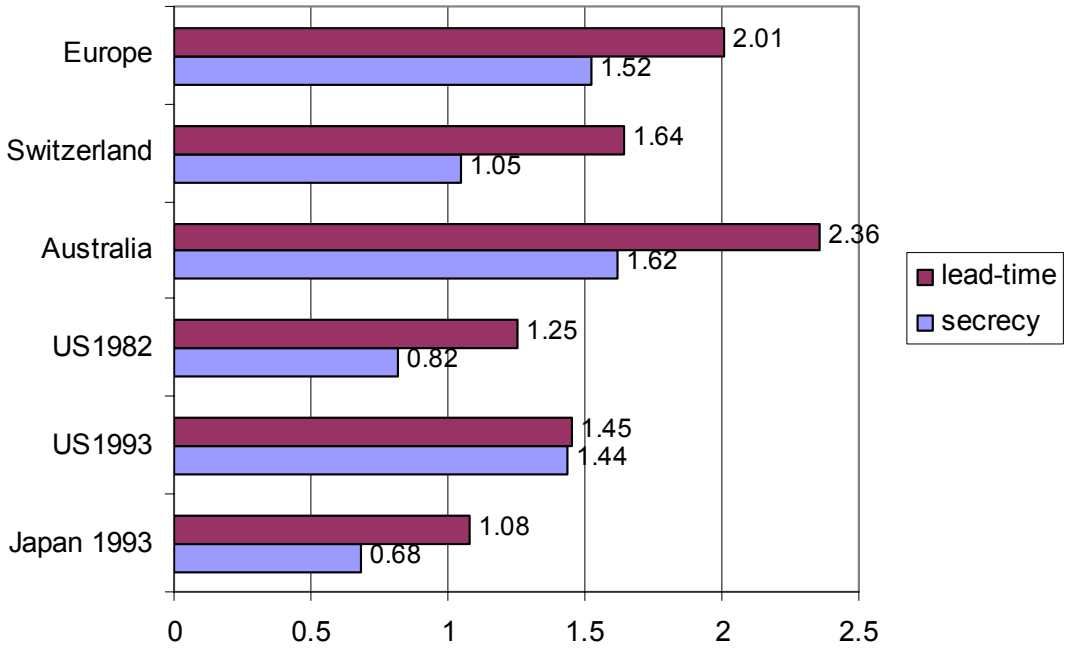
The choice of jurisdiction is an important strategic tool. Speed, costs, quality of judgements and procedural specialities are only some factors the litigator takes into account when deciding in which available court success is most likely. But litigation in general is more attractive, where the relevant market is bigger. The USA is the world's biggest biotechnology market. Consequently, for any overseas litigation it is of high importance. In addition, the US system appears more flexible, for example it allows contracting attorneys on a success-profit basis, including the great jurisdictional disadvantages of such a system. Remarkable is that Japan is second after the USA as the country with the highest number of patent applications. However, there is no culture of litigation in Japan and the Japanese system is not very transparent for foreigners.

5.4 Appropriation methods

Concerns about the extent to which the level of secrecy has increased, together with the slower pace of research in the biotechnology sector have grown. Research in other industries and countries has revealed that firms predominantly rely on mechanisms other than patents to protect their innovations (Mansfield, 1986, Levin et al., 1987). The relative importance of lead time advantages and secrecy in

comparison with patents in Figure 18 from a number of surveys shows, in the case of Europe (including innovative firms from Norway, Belgium, the Netherlands, Luxembourg, Ireland, Denmark and Germany) that secrecy (lead time advantage) is 1.5 (2) times more important than patents for earning competitive advantages from product innovations. The findings in Figure 18 also suggest that secrecy and lead time advantages are more important than patenting in Switzerland.

Figure 18 - Relative importance of secrecy and lead-time for earning competitive advantages from product innovations (a value of '1' means that the importance is equal to the importance of patenting)



Source: European Commission 2000, page 61

In the questionnaire for this study, one objective was to evaluate the overall importance of patents in comparison to alternative protection measures in the biotechnology sector in Switzerland. Participants were asked to assess the importance of different methods for protecting their inventions (Figure 19). The answers to this question show that patents are very important to protect inventions for the Swiss biotechnology industry. At the same time secrecy is almost as important as patenting as a protection measure when used together with lead-time advantages[11].

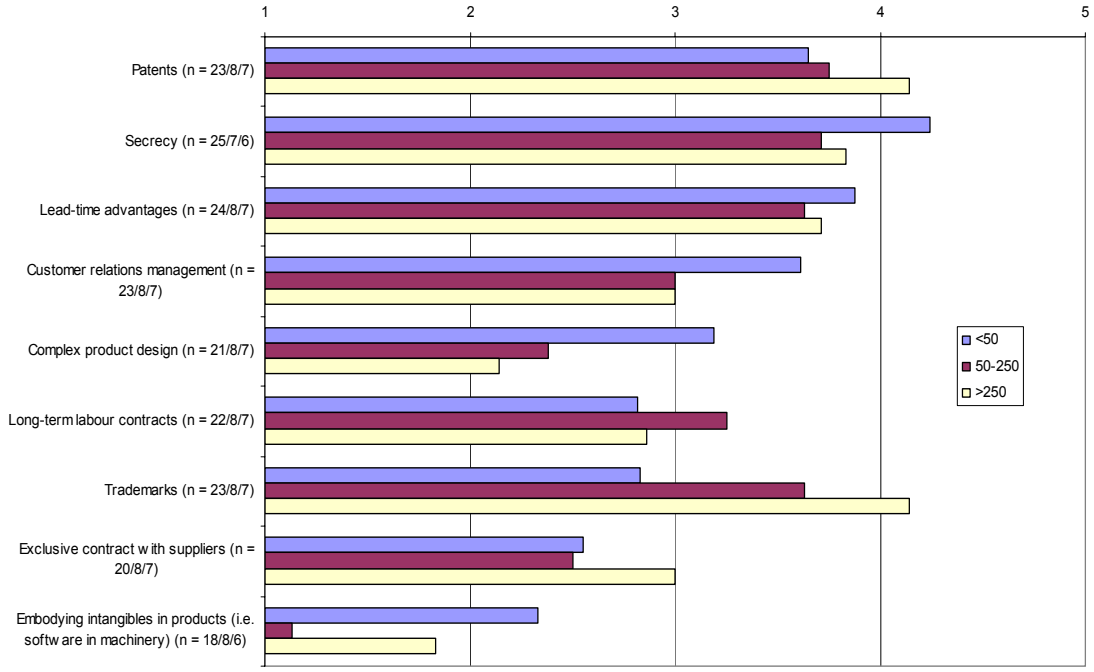
Not all inventions of economic usefulness are patented nor are they patentable and often secrecy is considered a more appropriate tool for protection, especially where product life cycles are relatively short.[12] This high rating of secrecy against patenting

[11] The high importance of lead-time advantages as a protection tool has also been confirmed in another study. See Blind and Thumm 2003, page 7, as well as Blind et al., 2003. In the latter survey for Germany only patenting active companies with more than 3 patent applications were interviewed. It is noticeable that regardless of the strong bias towards patenting in that sample, lead time advantage appears as the most important means of protection.

13 Various surveys demonstrate that manufacturing firms estimate secrecy higher than appropriation methods. Arundel et al. (1995), Arundel (2001), and Harabi (1995).

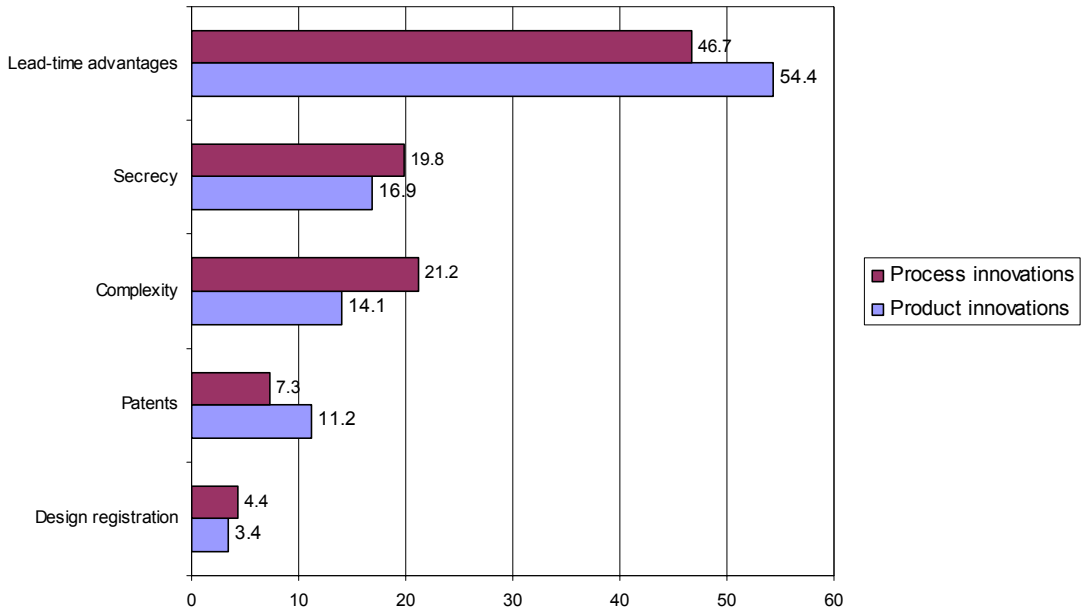
has been confirmed in various surveys with manufacturing companies (Levin et al., 1997, Cohen et al., 1998). Complex product design as a protection tool is less important than in survey findings for other industries. For research institutes, out of the given range of protection measures, only patenting plays an important role (Annex 11). In a survey of US companies, Cohen et al. (2000) found that patents are very important in the chemical sector, whereas in the manufacturing industry, in electrical machinery and medical instruments, secrecy is the most important protection measure.

Figure 19 - Swiss survey, importance of different methods to protect inventions or innovations (1=not important, 5=very important), only companies



Results from the EU Community Innovation Survey (CIS) with 2,849 R&D firms show that lead time advantages are the most important appropriation method, followed by secrecy, the complexity of product design and, finally patents. In general, secrecy is more important with process innovations, whereas patents are more important for product innovations. Figure 20 illustrates these findings from the Community Innovation Survey.

Figure 20 - Results from the EU Community Innovation Survey (CIS): Percentage of 2.849 R&D firms which give their highest rating to each appropriation method



Source: Arundel 2001

In the Swiss biotechnology survey patents together with secrecy are the most important protection tool. Patents are extremely important especially to protect the inventions of small companies (13 out of 27 small companies gave the highest ranking to patents as a protection measure). Economically important patents can be of utmost relevance as a bargaining chip or for achieving licensing revenues for small companies. Customer-relations management is also noticeably important to small companies, whereas trademarks are more important for big companies.

A component analysis revealed three general profiles for companies in their use of various types of protection methods (Table 1): Companies which use alternative protection measures, such as long term contracts, lead time advantages, customer relations management, exclusive contracts with suppliers, complex product design and the embodiment of intangibles in products (component 1); companies which use predominantly patents and secrecy (component 2); and companies relying on trademark protection (component 3).

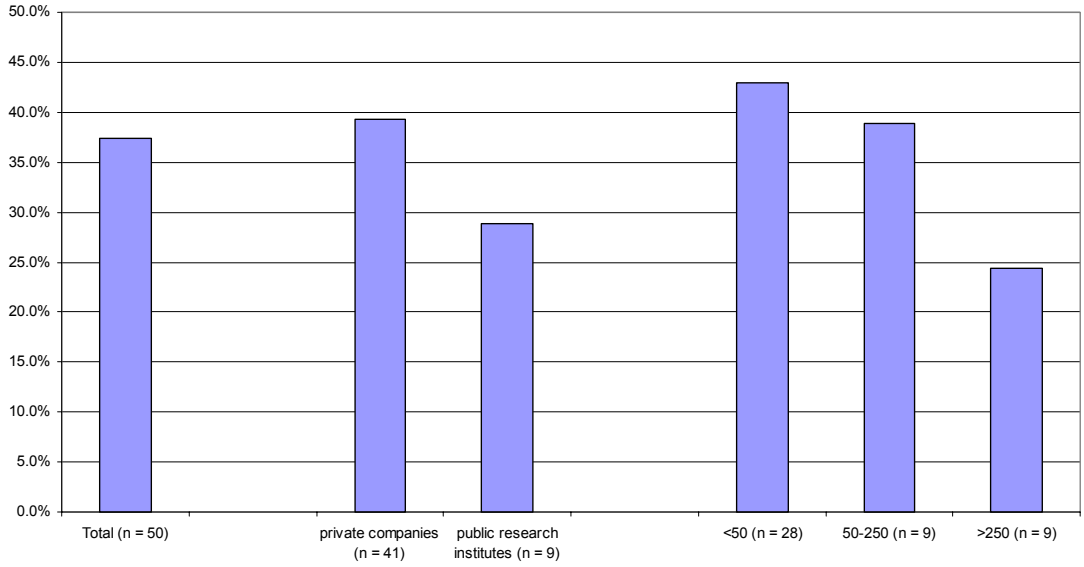
	Component		
	1	2	3
patents	.162	.681	.487
trademarks	.354	.149	.727
secrecy	.166	.742	-.277
long-term contracts	.708	-.301	.174
lead-time advant.	.605	.444	-.159
customer relations	.716	-.202	-.290
exclusive contract	.720	-.370	.401
complex desing	.663	.361	-.287
intangibles in products	.661	-.258	-.316

Table 1 - Swiss survey; component matrix, Principal Component Analysis

The remarkable high use of secrecy (with an average of 37%) in conjunction with patent protection is a key characteristic of the Swiss biotechnology sample where secrecy does not seem to be mutually-exclusive with patents. Usually in similar studies for other industries the level of secrecy is lower (compare Arundel, 2001 and Blind and Thumm, 2003). For process innovations secrecy is more important and its level of importance turns out to be independent from the firm size. For product innovations, there is also a high rate of secrecy. This could be because secrecy is preferred during the pre-market development phase which gives the firm time to refine its invention and build up lead-time advantage over competitors. Bigger companies tend to be more familiar with formal appropriation methodologies and consequently for product innovations, the importance of secrecy decreases with the firm size (Arundel, 2001).

The Swiss sample confirms this finding: The level of secrecy (relevance of patenting) is directly related to firm size. However, there are good reasons, especially for small firms, to make more extensive use of the patenting system. Big companies can use their marketing strength to create lead-time advantages and do not depend as much on the appropriation mechanisms of patents as small firms. Small firms usually lack strong marketing networks and patents offer a good opportunity to recoup their investments in innovation. Raising awareness on this issue would be an important task for innovation policy. The combination of both patenting and secrecy might accomplish the particular needs of the biotechnology industry. Figure 21 shows that research institutes usually use secrecy to a lower degree; small companies, with 45%, rely strongly on secrecy:

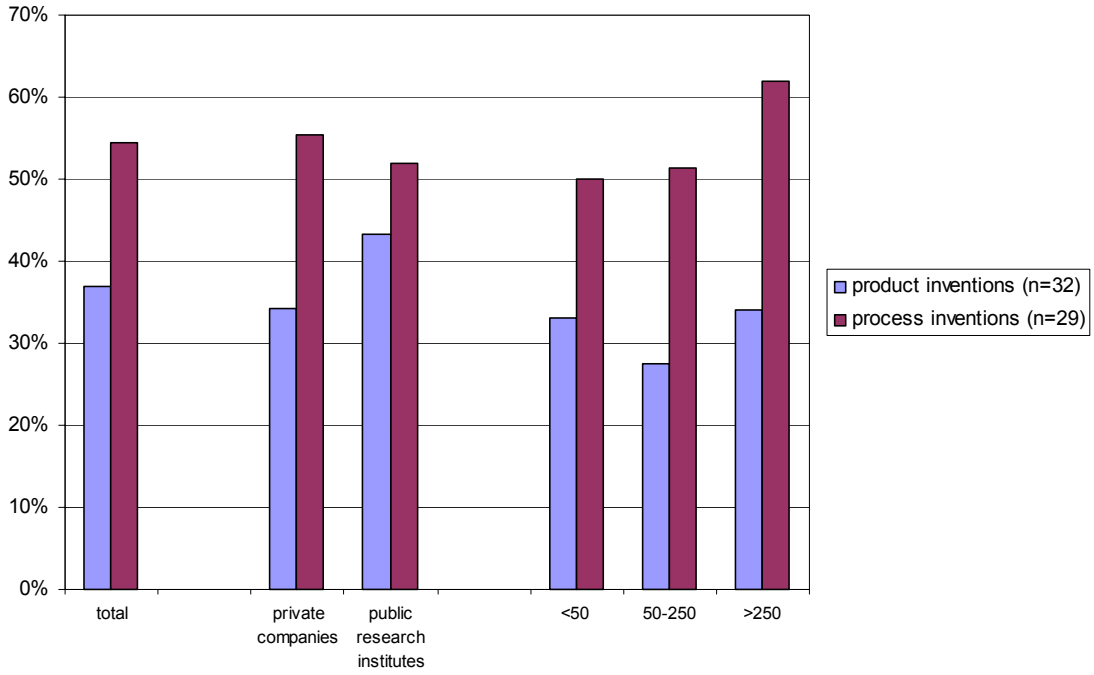
Figure 21 - Swiss survey; percentage of patentable inventions not patented



In an open question, survey participants were asked for the reasons to keep patentable inventions secret rather than patenting them. The answers showed that although they try to patent as many inventions as possible with a view towards the whole patent portfolio seeking protection, where individual patents would increase the value of the portfolio. At the same time they made it clear that in order to keep costs low, they have to carefully evaluate inventions. In particular, firms prefer to keep their inventions secret in those cases where the commercial exploitation is too small for patenting. Small and medium sized companies also mention filing costs as another reason not to use the patent system. Even though the value of publication as an alternative measure to patenting was not explicitly mentioned, it was considered useful to omit the blocking by others. Deciding whether to patent is not only an issue at the beginning of the innovation process. In the course of the priority year firms have to reconsider carefully if they want to continue with their application.

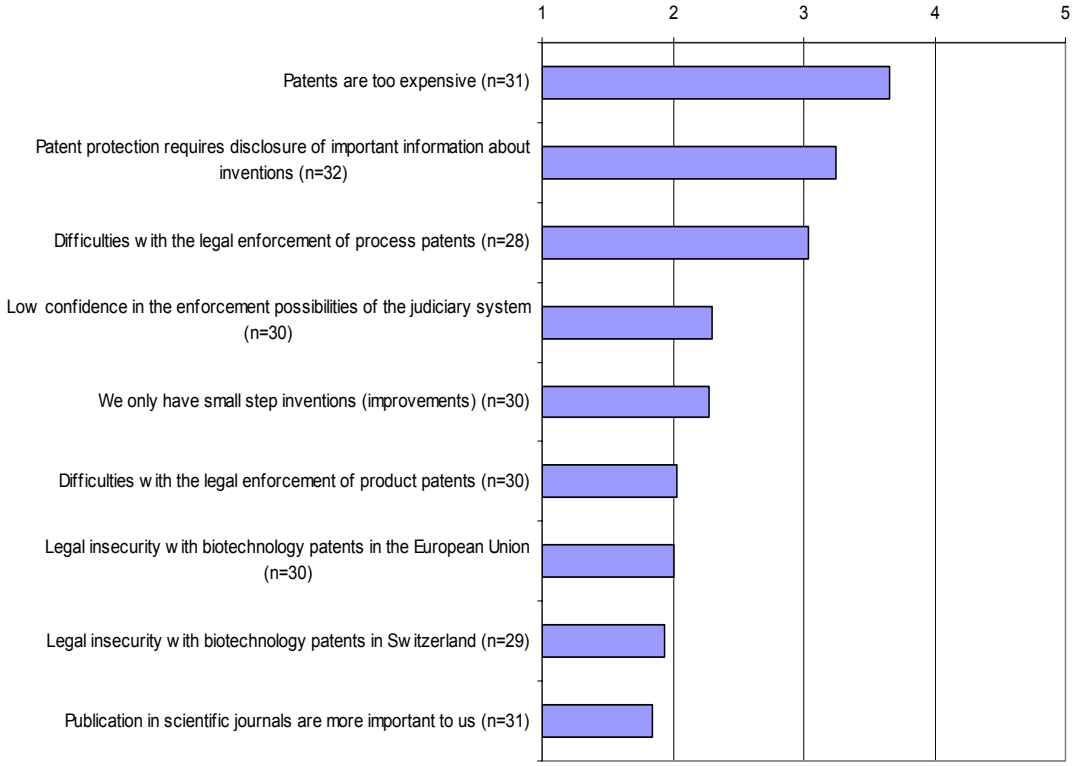
Particular reasons why firms do not make use of the patent system are that patenting is too time-consuming, that it requires a lot of expertise, that in the view of some companies biotechnological patents can be circumvented more easily than purely technical inventions and that keeping patents alive is very expensive. In the case of infringements it was found hard to enforce patent rights. High costs together with a high investment in time are only worth while if they promise a potential reward.

Figure 22 - Swiss survey: percentage of patentable product/process inventions not chosen for patenting during the period 2000-2002



In the follow-up questionnaire participants were asked to differentiate between product and process inventions with respect to secrecy. The 33 total answers is only a sub-set of the total sample of 53 entities, which explains why some numbers are different in Figure 21 than in Figure 22. The differentiation makes it clear that the level indicated in the first survey of 37% is for product inventions. The level for process inventions is much higher with on average 54%. Process inventions are harder to enforce than product inventions. Companies in the survey made it clear that, whenever process inventions seem not to be controlled they prefer to keep them secret, although they recognize that this strategy bears a risk considering the high fluctuation rate of employees. For process inventions the level of secrecy increases with the firm size to over 60% for big companies. In a further step in the follow-up questionnaire, participants were asked to indicate their motives for not patenting potentially patentable inventions.

Figure 23 - Swiss survey: relevance of motives for not patenting potentially patentable inventions (1=not relevant, 5=very relevant)



The high price of patenting and the fact that patent protection requires the disclosure of important information about the inventions are the most important reasons why biotechnology entities in Switzerland prefer not to patent potentially patentable inventions. Whenever secrecy is given preference it is not a matter of legal insecurity, either in the European Union or in Switzerland, and it is not due to difficulties with the legal enforcement of product patents.

The six research institutes participating in the second survey indicate a certain preference towards publishing in scientific journals rather than patenting. This indicates a persisting unawareness about the patent system and its economic scope in public research institutes. For private companies it is a non-issue. Public research institutes consistently rated a score of 5 for patents being too expensive. Big companies are in particular concerned about the fact that patent protection discloses important information about their inventions (see Annex 12) and claim difficulties with the legal enforcement of process patents.

6. Patenting Strategies

6.1 Strategic patent filing

The first prerequisite of strategic patenting is the active observation of competitors' patenting portfolios, which is already necessary in order to identify market niches and to place products in the right place on the market. The various possibilities for strategic uses of patenting include:

- Offensive use;
- Defensive use;
- Negotiation;
- Improving the image of the company.

Patenting more does not necessarily lead to more innovation. Strategic patenting covers the use of patents for purposes other than protecting an invention from being copied. There are various indications but little reliable proof of the increasing strategic use of patents. Schankerman (2003) found that in small patent portfolios the probability of getting into litigation for an individual patent is much higher than with bigger patent portfolios. This could be an indication that most of the patents in large patent portfolios are used for reasons other than protecting one's own technology. The purposes for which companies make use of their patent portfolios are very diverse, but generally fall into the following categories:

- Protection from competition;
- Complementary protection;
- Safeguarding future technologies;
- Basis for alliances.

The first of these purposes is the closest to the original intention of patents, i.e. to prohibit other entities than the inventor from commercializing the patented technology. Complementary protection is the protection around a core technology which itself has no direct commercial purpose but aims at protecting a key patent that needs a higher degree of protection. The associated area can be safeguarded by patenting all possible varieties of one original invention. Examples are patents on all possible mixtures of a highly efficient chemical substance. Large pharmaceutical companies file as many patents as possible in one technological sector. The intention is to occupy the entire field, even though individual patents may not be of interest ("blocking scenario").

Following the 'fence strategy', another form of patent blocking, firms patent substitutes for core inventions in order to maintain exclusivity over the technology. Such behaviour makes the technological field unattractive for any potential market entrant. In fact, this is strongly recommended by experts, since otherwise firms may be excluded from future technological development by their competitors. The principle of protecting the associated area of an invention is also an economic need since, if not done by the inventor, any competitor can take the initiative and place a patent in the technological niche.

Similar strategies are recommended with respect to the protection of future technologies. Here, a company has to make sure that it has a prior claim to a specific

area of technology and that it will participate in the future commercialization of this technology without relying on the patent portfolio of a competitor.

Patents as a basis for alliances aim at moving the holder into a better negotiating position against competitors (swap patents). An example is the patenting of diverse mixtures of an invented chemical substance. In order to prevent the patenting of an invention by a competitor, the inventor includes in the patent application the name of all substances invented, a cross-dependency is created and, thereby, a better negotiation position for cross-licensing is established.

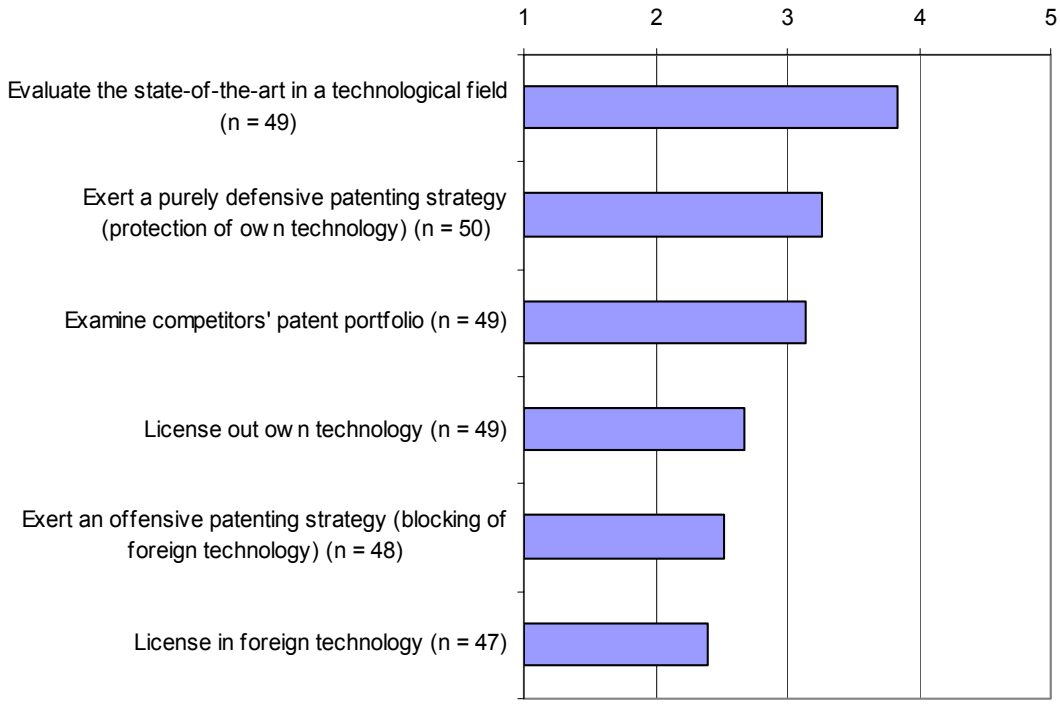
All the mentioned purposes can be used in a defensive way as well as in an offensive way aimed at hindering competitors rather than protecting own inventions. This depends very much on the coherent patenting strategy of a single firm. The various strategic uses of patenting are not limited to large firms. Small and medium-sized biotechnology companies, naturally restrained by their economic resources, also use strategic patenting in order to achieve competitive advantages without expending too much own resources. In a way, small companies depend even more on patenting than larger ones, since often their patent portfolio is the only economic asset they have.

The social costs of strategic patenting are to a large degree unclear. In general, there is nothing wrong with strategic patenting, since in a way, patents are always a strategic tool. Impact of strategic patenting on the creation of innovation and wealth is important. Strategic patenting could have a serious detrimental impact on access to patented information and, as such, build barriers to market entry for competitors, most likely with a negative impact on innovation. At the same time the use of patenting could also contribute to the spread of patented technology and as such have a positive influence on innovation. We have little empirical evidence for the relationship of strategic patenting and innovation so far, but need to understand more about the impact of strategic uses of patents especially upon market entry.

Empirical evidence of strategic patenting is more available in the telecommunication sector than in biotechnology. In the telecommunication sector, there are clear indications of patent portfolio races and of patents being primarily used not to protect, but to trade and which are quite likely to hinder effective competition by too strong monopolistic market positions. Some studies have argued that stronger patent rights in the telecommunications sector may hinder the development of effective competition of telecommunication markets, representing a great potential risk (European Commission, 2002, and Hall and Ziedonis, 2001).

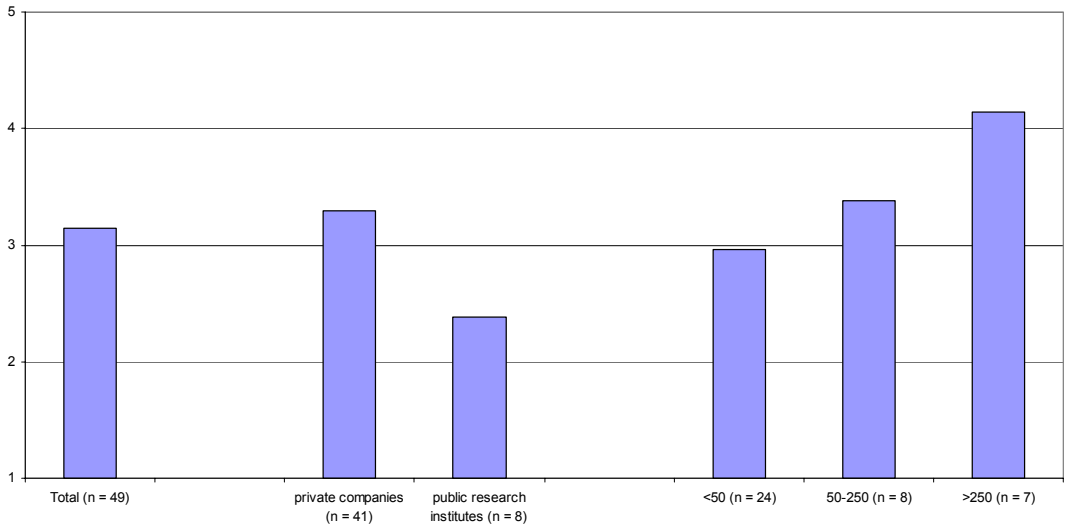
It is difficult to achieve reliable statistics on strategic patenting. It is more an area where a case study approach promises interesting insights. The participants in the Swiss survey were asked to which degree they practise a variety of patenting strategies, listed in Figure 24. The results show that all participants, regardless whether they are from public research institutes or private companies actively evaluate the state-of-the-art in a technological field. This is a positive expression of awareness in the sector that should help to reduce legal cases and conflicts. The use of this preventive measure rises with the firm size. Most participants indicate as well that they exert a purely defensive patenting strategy in order to protect their own technology. This answer is in agreement with the previous answers for reasons why firms patent (see again Figure 13).

Figure 24 - Swiss survey: degree of practicing patenting strategies (1=never; 5=very often)



Examining competitors' patent portfolio is a more offensive way of structuring one's own patent portfolio. Most participants in the Swiss survey indeed look at other portfolios, although more practised by big companies than by small ones and even less by research institutes.

Figure 25 - Swiss survey: To which degree do you practice the following patenting strategies? Examine competitors' patent portfolio (1=never, 5=very often)



Nevertheless, there are various small companies actively engaged in the examination of their competitors' patent portfolios (three small companies even indicated that they practise this strategy very often). A few small companies engage in all forms of patent strategies

This becomes even more obvious when looking at those survey participants that exert an offensive patenting strategy, which also includes the blocking of foreign technology i.e. that prevents rivals from patenting related inventions. On average participants do not practice or do not indicate to practice this strategy. Only big companies, together with one small company, revealed that they also try to be active against their competitors in the patenting battle. This finding sharply contrasts with the findings of other studies from the United States and Japan, where firms are strongly driven by the wish to block competitors. In the United States, for product innovations, 80% of the respondents report blocking as a motive for patenting while in Japan it is even 90% (Cohen et.al. 2002, p.1358).

The moderate degree of strategic patenting in the Swiss sample could be specifically related to the biotechnology industry. According to other studies, the degree of strategic patenting depends on whether the relevant industrial sector is a 'complex' or 'discrete' industry. In a complex product industry, products are protected by numerous patents. In this sense the computers and communications industry are a complex product industry. In discrete product industries, products are protected by relatively few patents, this could include the drugs or chemicals industry.

According to Cohen et al. (2002), strategic patenting is limited to complex product industries. Cohen et al. find that in complex product industries patents are used to block the rival use of complements in order to (1) assure a strong status in cross-licensing negotiations, (2) to access rival technologies and (3) to gain freedom to operate. In discrete product industries, patents are used to block substitutes by creating patent fences.

Biotechnology as such is more similar to the chemical industry and hence more of a discrete character. This could be a reason for the low degree of strategic patenting activity in the sample. Another reason could be the lower involvement in strategic patenting issues in general in Europe in comparison with the United States. The fields of DNA patenting, and genetic testing in particular, are different, which will be explained later on. These biotech subfields show complex structure similar to that of complex industries, which could be the reason for the more serious problems of patent thickets and royalty stacking in the biotechnology field.

Only a few remedies against strategic patenting are imaginable, like examining carefully novelty, inventiveness and industrial applicability requirements. This would reduce the overall number of patents, especially those which are not for primary economic use (European Commission, 1999). According to a policy-oriented workshop on strategic patenting organized by the European Commission (European Commission, 2003), policy options to reduce the costs of strategic patenting could be the following:

- Raise the standards for a patent;
- Limit extensions of patent rights;
- Strengthen the research exemption;
- Develop appropriate patent policies for public sector research.

6.2 Licensing strategies

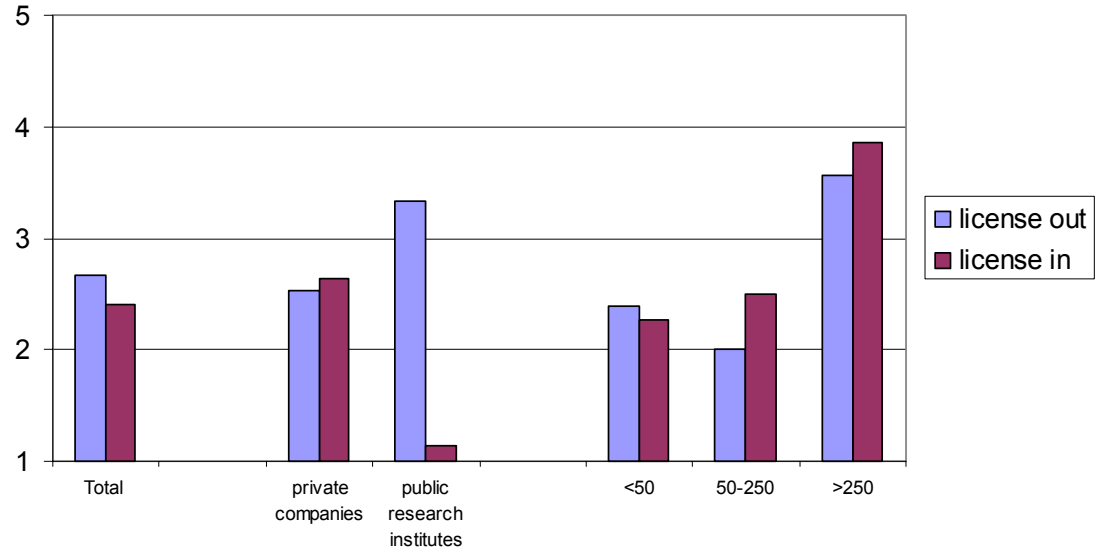
While issues of patentability are vehemently discussed in the public, experts stress (OECD 2002) that licensing practices for genetic inventions are rapidly becoming the more contentious problem. Industry understands patents above all as an instrument for making money. Patents are used for licensing and their aim is to exploit them as much as possible for economic benefit. More and more companies are realizing that aggressively asserting their patents can generate considerable business advantages. Many companies spend large amounts of money in identifying the economically relevant patents in their patent portfolio (portfolio audit), as well as in cluster and bracket analysis, where clustering around the core technology assures that a core technology has been protected.

Efforts have to be made to oversee the patent's ageing process (i.e. the number of years left on a company's patents), to track which inventors are still with the company (or if they work with a competitor), and of course, most importantly to identify candidates for out-licensing. Therefore, different approaches to identify licensees are followed; either through personal in-depth contacts or through a "shotgun approach", i.e., -flooding all the competitors in a particular technology with patent license solicitation letters.

Licensing and the generation of licensing revenue as part of an intellectual property strategy play an important role for companies in the United States and in Japan (Cohen et al. 2002). Other surveys (OECD 2003) report increased overall licensing activity, with a trend towards inward-licensing in the information technology sector and outward licensing in the pharmaceutical sector. The Swiss sample reveals - surprisingly - that companies in Switzerland are not very active in licensing in or licensing out. A closer look shows that it is an important issue for big companies. It seems to be less important for the majority of small companies, although for some small companies licensing out is of utmost importance.

Research institutes are not very active with the licensing in of technologies, but it is very important for them to license their own technology to others and to achieve third party financing this way (Figure 26). This finding also corresponds with the analysis above (Annex 21), where research institutes indicated that the generation of licensing income is an important motive for them in applying for a patent. Big companies mentioned that licensing often concerns non-core aspects of technologies and that such licenses can be difficult to supervise.

Figure 26 - Swiss survey: To which degree do you practice the following patenting strategies? Licensing in foreign technology; License out own technology (1=never, 5=very often)



Cross-licensing, patent pools and consortia are remedies to reduce transaction costs with licensing and to overcome secondary problems of too much patenting, such as patent thickets and the anti-common tragedy. Cross-licenses are negotiated when each of two companies has patents that may affect the other's products or processes. Rather than blocking each other and going to court the companies come to a cross-licensing agreement.

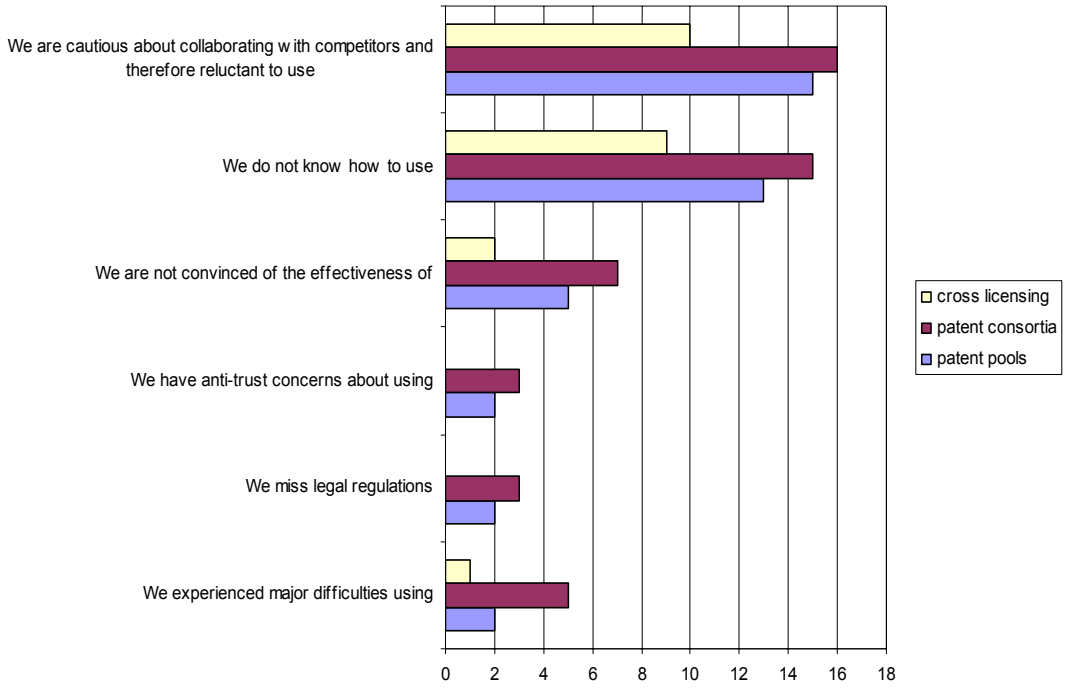
When two or more companies control patents necessary to make a given product, a patent pool or a package license can provide a solution. Under a patent pool, an entire group of patents is licensed in a package, either by one of the patent holders or by a new entity established for this purpose. Patent pools are a possible remedy against the abusive uses of strategic patenting, against patent thickets and royalty stacking. They help to integrate complementary technologies, reduce transaction costs, clear blocking positions, avoid costly infringement litigation and promote the dissemination of technology.

Unfortunately they are rarely used in biotechnology[13]. To establish and run patent pools efficiently, and to promote their general advantages, some conflict potentials and possible disadvantages, like their misuse as a price-fixing mechanism, have to be taken into account and a number of recommendations should be considered (Blind et al. 2002). Patents should be pooled early in order to avoid constellations with two or more pools driven by different interests. It has proven useful to include public non-profit research institutes as a key gravitational force for creating patent pools, since they can more easily balance the often controversial interest of the companies. Blind et al. concluded that it also has been useful to involve companies in patent pools which are successful in distributing new products and technologies since this can guarantee the successful acceptance of a new standard in the market.

[13] Patent pools are more common in the field of information technology. An example for a successful patent pool is the MP3 format for music files developed under the framework of an EUREKA project as a cooperation between the German Fraunhofer Institute and companies like AEG, Bosch, Philips and Thompson. The success of the technology was due to an early stage planning of a patent pool.

A patent consortium is a non-profit entity whose goal is to create new knowledge and to make it publicly available. Upstream inventions are included in the pool in order to permit downstream inventions for all members without royalty payments. In order to exert the level of more advanced tools of patenting strategies, the questionnaire asked to what extent the participants had had experience with cross-licensing, patent pools and patent consortia. The answer was that the Swiss biotechnology industry has almost no expertise with these tools. Only a few bigger companies indicated a slightly higher degree of expertise and two small firms indicated advanced experience with cross-licensing and patent-pools. In order to investigate this highly important field and to retrieve more information on the potential of these remedies, the participants of the follow-up questionnaire were asked about the reasons why there seems to be such a low level of experience with cross-licensing, patent pools and patent consortia in Switzerland. The evaluation of the answers is given in Figure 27:

Figure 27 - Swiss survey: reasons for the low experience with cross licensing, patent consortia and patent pools (counted answers)



It shows that many biotechnology entities do not know how to use cross-licensing, patent consortia and patent pools in Switzerland and that many are cautious about collaborating with competitors and are therefore reluctant to use these remedies. Anti-trust concerns are not the reason for their concerns. Only a few companies are concerned about experiencing major difficulties while using these remedies.

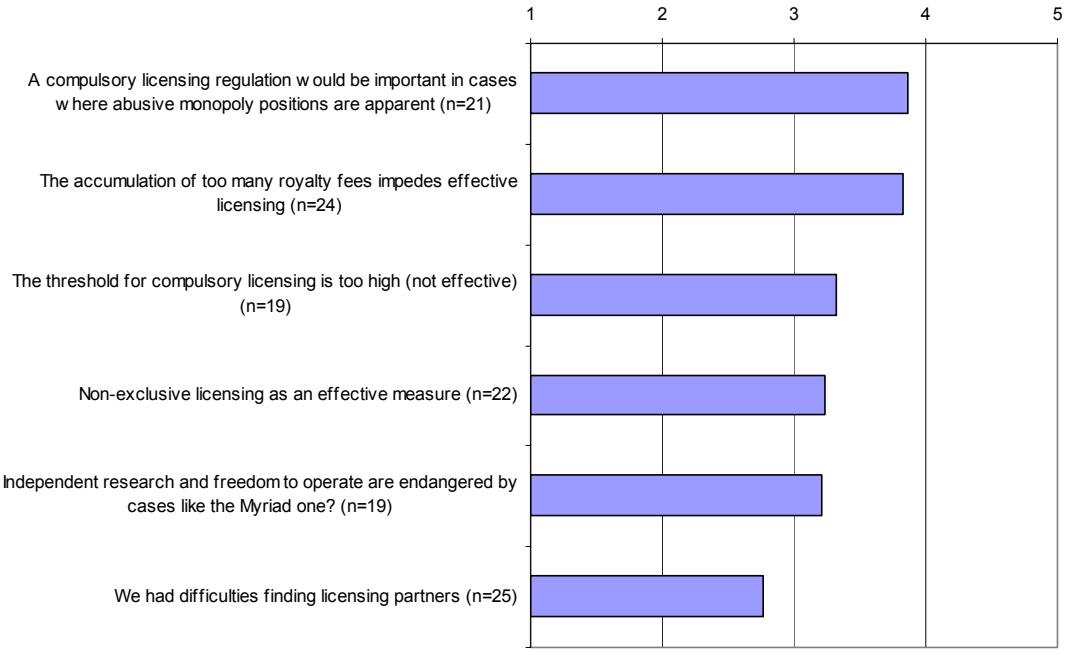
Scenarios developed in other studies (e.g. Hall and Ziedonis, 2001), such as patents become weapons in mutually reinforcing, while firms feel forced to patent because they have to protect themselves from suits or because they need patents as bargaining chips in negotiations, cannot be confirmed for the case of Switzerland.

In an open question, field participants could briefly explain which patenting and licensing strategies have been commercially successful in their companies. Big

companies indicated that they intend to generate a broad own patent (application) portfolio in order to cover all technical aspects of their products. Licensing includes what one participant called 'straight patenting' the acquisition of exclusive rights on a drug in development. Usually, respondents indicated that they use patents with a focus on the protection of their technologies. Small companies also use patents in order to secure research contracts with their clients - large pharmaceutical drug companies - and try to license out their patent applications and know-how. A stronger relationship than pure licensing in/out between small and large companies would be the establishment of strategic alliances, where small firms rely on the large sales forces and development potential of large companies.

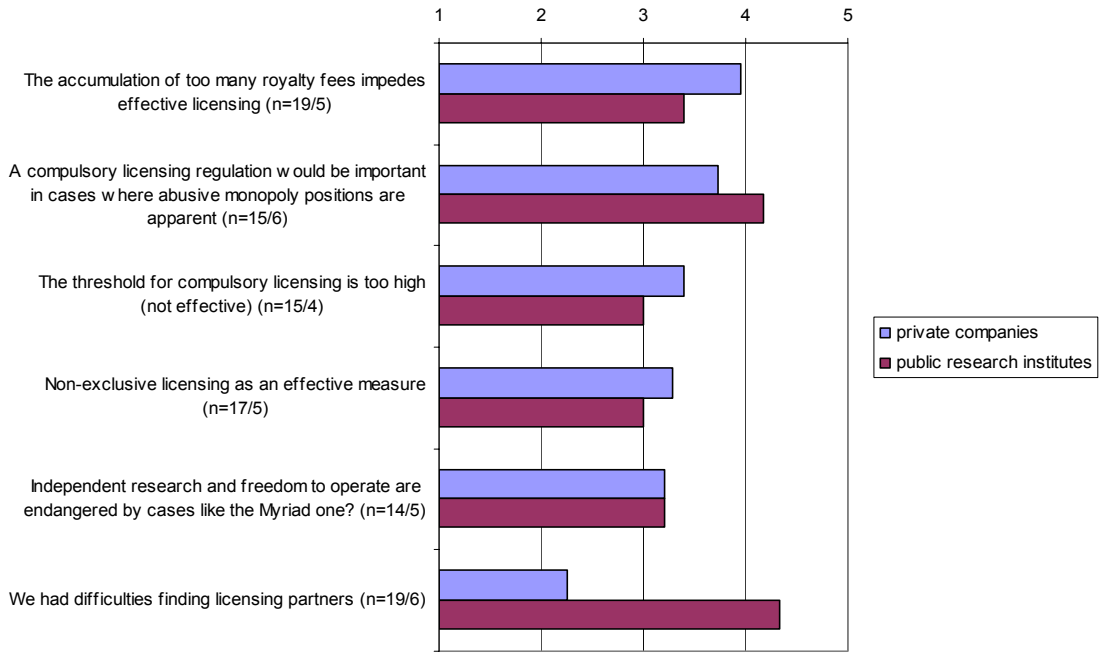
The follow-up questionnaire tried to investigate in more detail the importance of licensing patents for biotechnology companies and research institutes. A number of measures with respect to licensing were evaluated. Figure 28 makes clear that a compulsory licensing regulation would be important in those cases where an abusive monopoly position is apparent as well as where the accumulation of too many royalty fees could impede effective licensing. The threshold for compulsory licensing was assessed to be too high and hence not effective in general. Usually, companies in the sample had no difficulties with finding licensing partners.

Figure 28 - Swiss survey: evaluation of some measures/statements with respect to licensing (1=no agreement, 5=total agreement)



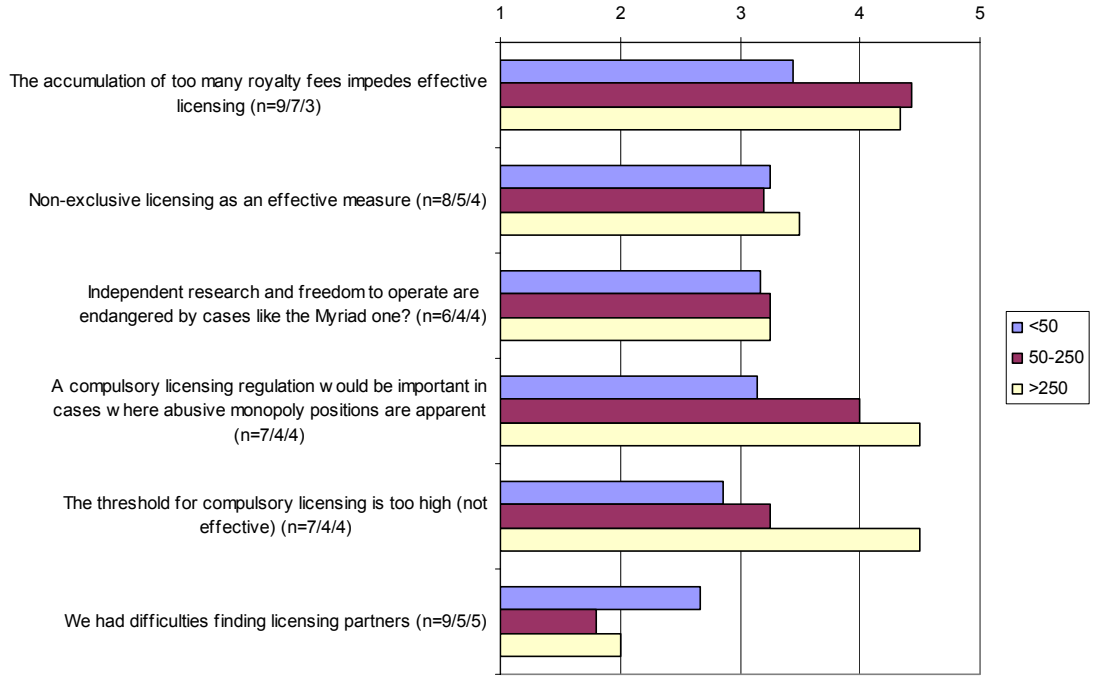
Only research institutes indicated that they had difficulties with finding licensing partners (Figure 29). Research institutes in particular are convinced that a compulsory licensing regulation would be important in those cases where abusive monopoly positions are apparent.

Figure 29 - Swiss survey: evaluation of some measures/statements with respect to licensing (1=no agreement, 5=total agreement)



Bigger companies believe that the accumulation of too many royalty fees impedes effective licensing (Figure 30). Companies in the sample with more than 250 employees believe that a compulsory licensing regulation would be important in cases where abusive monopoly positions are apparent.

Figure 30 - Swiss survey: evaluation of some measures/statements with respect to licensing (1=no agreement, 5=total agreement), only companies



Participants demand that there should somehow be an obligation to license basic research tool patents on a non-exclusive basis under reasonable and non-discriminatory terms. Big companies also believe that the threshold for compulsory licensing would be too high. Small companies had more difficulties than bigger companies in finding their licensing partners.

7. The European Legislation

Protection of intellectual property is essential for biotechnology firms. The debate on what, how and when biotechnological inventions can be protected by legal means is continuing. There is a need for a coherent European legal framework for the protection of biotechnological inventions. Different legal regulations among European countries may lead to trade problems within the European internal market and industries might hesitate to invest in R&D or shift their research base in biotechnology to other countries. There is still a considerable public debate ongoing on the scope of patentability of biotechnological inventions.

The European Union directive 'on legal protection of biotechnological inventions' (98/44/EC) wants to establish the guidelines for legislation in Europe in this respect. Since the first draft it took more than ten years to adopt the directive. Finally, in May 1998, the European Parliament accepted the Commission's latest proposal with 432 votes in favour and 78 against (mainly the green party) and 24 abstentions. The EU countries had time until July 2000 to adopt it. Already in 1998, the Netherlands, with the support of Italy and Norway, brought an action for annulment of the Directive 98/44/EC to the European Court of Justice. By an injunction in July 2000 the European Court rejected the application. So far only Denmark, Finland, Greece, Ireland, Spain and the United Kingdom have implemented the Directive into their national laws. The other EU member States are currently in different stages of progress. In some countries (Austria; Germany, Italy, Luxembourg, Netherlands, Portugal) the discussions are already taking place before the national parliaments. In Belgium, France and Sweden, a draft law has been given the go-ahead, but it has not yet been possible to submit it to the national parliaments.

The directive explicitly emphasises that it does not create any specific patent law for biotechnological inventions but is only making adaptations and amendments which the national legislator must implement. National patent law remains the essential basis for the legal protection of biotechnological inventions, providing that it has been adapted in certain specific respects to take adequate account of technological developments involving biological material.

7.1 Basic principles of the European biotechnology directive

Article 3 of the directive extends the general prerequisites of patentability to biological material (defined in Article 2) and claims that such material is in general patentable even if it previously occurred in nature, providing the industrial application is clearly specified in the patent application. Article 4 of the directive tries to ensure consistency with Article 53b EPC by excluding from patentability plant and animal varieties and essentially biological processes for the breeding of plants and animals. Exceptions are possible for cases that are not technically confined to a particular plant or animal variety.

Article 5.1 establishes the principle of non-patentability for the human body and its parts. Paragraph 2 of the same Article defines exceptions for isolated elements of the human body which are produced "by means of a technical process" and explicitly includes sequences of genes. This article also gives a clearer position on what parts of the human body can be regarded as patentable inventions and not mere discoveries. A variety of ethical and public policy objections are grounds for exclusion, in particular the following:

- procedures for human reproductive cloning;
- processes for modifying the germ-line genetic identity of human beings;
- methods in which human embryos are used;
- processes for modifying the genetic identity of animals which are likely to cause them suffering without any substantial medical benefit to humans or animals and also animals resulting from such processes.

Article 11 gives farmers the privilege of utilizing offspring from transgenic stocks without paying any royalties (the so-called farmers' privilege).

The European industry welcomes generally the new directive as an appropriate intellectual property structure and considers it to be a crucial factor influencing a company's decision to invest in and to use biotechnology (see Thumm, 2000). Experience from the USA demonstrates how important the patenting environment is for the development of the biotechnology industry. The real future effectiveness of the new directive and whether it will foster competitive advantage for Europe depends very much on its practical implementation by the EU member States.

7.2 Ethical principals

There are some major ethical concerns on the subject of biotechnological inventions. The main ethical criticism is based on worries that somehow 'life' itself is being patented in conjunction with a moral view that living animals should never be reduced to the status of an object of invention. For the evaluation of patenting from an ethical point of view, it makes a big difference whether genetic alterations are allowed for the freedom of science or whether they are part of an economic premium system, as in the case of the patent system. A famous case is the decision of the European Patent Office on the so-called Onco Mouse, where a patent was claimed for a genetically altered mouse by Harvard University. In this decision a patent was granted for a transgenic animal. The fact that the mouse in question does not occur in nature made the application for patent protection. The underlying argument against patent protection of living beings, however, is that animals should not be used as mere tools for human ends and, in particular, they should not be caused to suffer. The examination division of the European Patent Office justified the granting of a patent on the basis of its judgement that the likely benefits for cancer research outweighed the ethical concerns. This decision set the precedent for a utilitarian approach in which possible negative consequences are justified by the invention's usefulness to mankind.

Advocates of the biotechnology directive point out that "patenting life" *per se* is a meaningless notion as patent law does not allow the patenting of abstractions. A patent can therefore not be granted on "life". Normal application of patent law already excludes the following (Article 53 PCT):

- human beings;
- body organs, limbs, body fluids, and any other known part of the human body;
- nucleotide sequences elucidated by human genetic research and other molecules identified by such research in the human body in the their natural state.

The European biotechnology directive considers inventions where their commercial exploitation would be contrary to *ordre public* or morality as not patentable. It sets the level of *ordre public* high by explicitly excluding a variety of inventions from patentability in Article 6.

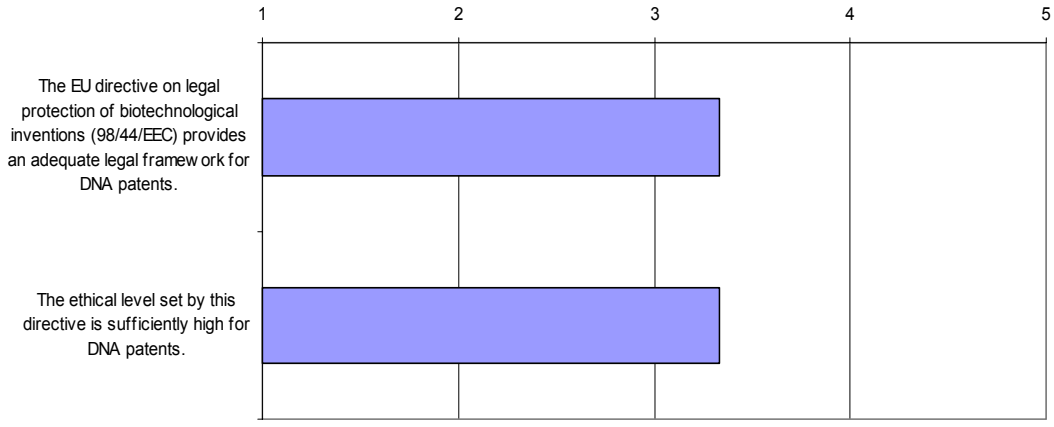
Other investigations confirmed that the exclusions from patentability due to ethical and moral reasons in Article 6 are welcomed by private companies and by public research institutes (Thumm, 2000, page 114). A working commission of the European Communities on the development and implications of patent law in the field of biotechnology and genetic engineering (European Commission, 2002b) found two questions deriving from the Directive 98/44/EC important for the further process of the implementation of the directive:

- The scope to be conferred on patents relating to sequences or part-sequences of genes isolated from the human body;
- The patentability of human stem cells and of cell lines obtained from them.

7.3 Assessment of the directive by the Swiss biotechnology industry

The participants in the Swiss sample moderately welcomed the directive (see Figure 31). The Swiss biotechnology industry in general agrees that the EU Directive on legal protection of biotechnological inventions (98/44/EC) provides an adequate legal framework for DNA patents. The survey participants also believe that the ethical level set by the Directive is sufficiently high for DNA patents. All patent intensive companies in the sample welcome the Directive to an above average degree. There are no differences in the degree of acceptance either between private companies and public research institutes or the different company sizes.

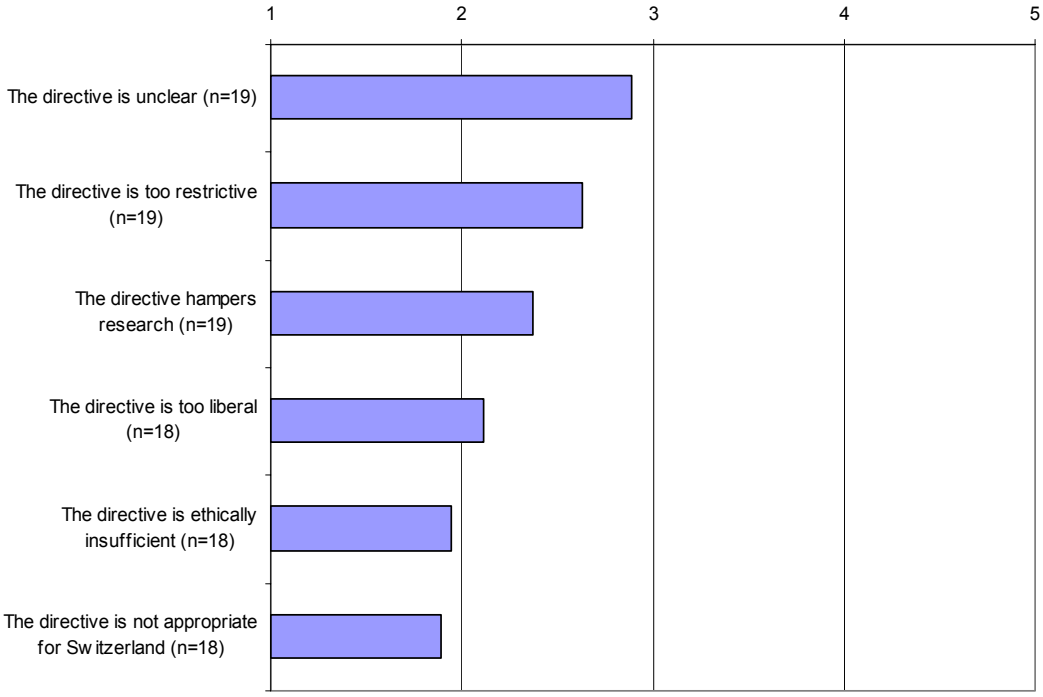
Figure 31 - Swiss survey: extent of agreement with the EU Directive on legal protection of biotechnological inventions (98/44/EC) (1=very low, 5= very high)



The moderate acceptance of the biotechnology directive led to inquire further the possible concerns of companies and research institutes. The survey participants were asked to what extent they share concerns with respect to the implementation of the EU directive in Switzerland. The results in Figure 32 make clear that in general there are no serious concerns about the Directive: neither that the directive would generally be inappropriate for Switzerland, nor that the ethical level of the directive is

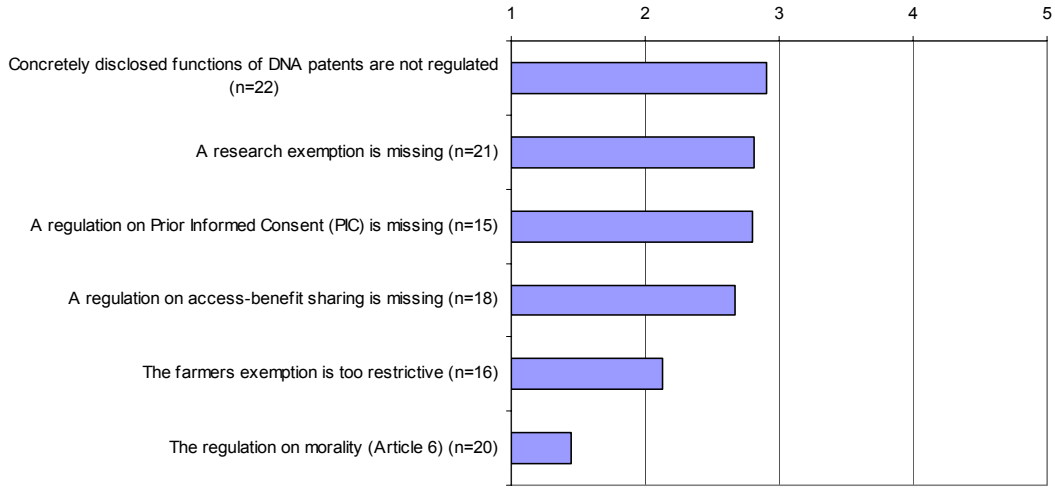
inappropriate. Only public research institutes mentioned concerns that the directive might in general be too unclear.

Figure 32 - Swiss survey: degree of concerns about the implementation of the EU directive on the legal protection of biotechnological inventions in Switzerland (1=no agreement, 5=total agreement)



The participants were asked to mention their concerns about certain concrete regulations in the directive. Responses revealed that there are no serious concerns (Figure 33). There are no concerns at all about the regulations on morality (Article 6) in the Directive or about the formulation of the farmers' privilege. Research institutes have no particular concern about any of the regulations. Only big companies complained about the lack of regulation of a research exemption while smaller companies were somehow dissatisfied that the concretely disclosed functions of DNA patents are not regulated in the directive (Annex 14).

Figure 33 - Swiss survey: do any of the following regulations of the EU directive on the legal protection of biotechnological inventions concern you? (1=no concerns, 5=many concerns)



8. Patents on Gene Sequences

8.1 DNA patents

With respect to gene patents two main concerns have been raised. First, the anti-commons problem (Heller, Eisenberg 1998), according to which numerous claimants lead to the breakdown and loss of collective surplus, which impedes development and commercialization of promising genetic inventions. Second, limitations by patented upstream foundational inventions on subsequent research and improvements.

The patentability of gene sequences is one of the issues that is vehemently discussed when it comes to biotechnological inventions. Economic theory postulates that patents are a facilitator for the diffusion of knowledge and innovation. However, recent studies found that too much patenting can also deter innovation (Heller, Eisenberg, 1998 and Hall, Ziedonis 2001). Especially DNA patents are criticized for being too broad with respect to potential follow up research or respectively, continued research in the relevant scientific area.

Another issue is the patentability of DNA sequences itself. Officially, gene sequences are in principal patentable once they are isolated, identified and made practically available together with a process to develop and apply them to practical use. The directive 98/44/EC confirms this position in Articles 2 and 5. According to these provisions, nucleotide sequences are patentable in principal, once they derive from genetic research and are isolated from the human body by means of a technical process. Concerns about the patentability of gene sequences usually come up for two reasons. First, their pre-existence puts into question the concept of novelty. Second, the inventive step for DNA patents diminishes with the reduced technological effort spent to identify gene sequences. The first objection was regulated for chemical substances in a positive way a long time ago. The latter would be a reason for careful examination of the inventiveness by the patent authorities. The EU biotechnology directive is relatively clear with respect to the patentability of DNA sequences. The disclosure of a mere sequence without indication of a function does not contain any technical information and is therefore not a patentable invention (recital 23), even if the method of manufacture is indicated. However, the natural pre-existence of biological material alone does not constitute a patentability obstacle (Article 3(2)). The directive also makes it clear that the industrial applicability of the DNA sequence has to be specifically disclosed already in the patent application and not in the course of the examination (recital 22) (see also Straus, 2003).

Naturally, researchers refrain from research in further uses of a gene when they know that it has already been patented by a third party. The perspective of being dependent on the patents of someone else in case a commercially usable invention can be developed can be sufficient reason for a company to turn down research on the specific functions of genes. Further concerns became known under the names of ‘anti-commons’ and ‘patent thickets’.

Heller and Eisenberg describe the ‘tragedy of the anti-commons’ as a situation where the necessary knowledge to conduct further research is covered by a large number of patents held by many firms. Transaction costs become too high to collect all the relevant information for further research, which results in an under-use of patented biotechnological information (anti-common). The preconditions for the anti-commons

are a growing number of patents, many biotechnology firms, increasing university patenting and the use of defensive patenting which decreases the freedom to operate. The anti-commons could be the reason why the patent system can impede the combination of new ideas and inventions by raising transaction costs for follow-on innovation and by providing an opportunity for rent seeking.

Patent thickets describe a situation in which a proliferation of gene patents can necessitate the negotiation of multiple licenses with increasing transaction costs to a level where they become socially inefficient. Workable solutions would be to negotiate licenses, to invent around, to challenge the relevant patents in court or to simply infringe, what has become known as the 'informal research exemption'.

A long-term harmful effect of patents on research and the innovative level of a country would not be in harmony with the original idea of patents as an incentive to overcome market insufficiencies nor could it be in the general interest of the innovation policy of a country. Empirical investigations (Walsh et al. 2003, Cho 2003 and Federal Trade Commission, 2003) found that access problems are real, especially with upstream inventions which are foundational and rival in use. In economic terms, the research access problem of patents would create short-term monopolies, which may become long-term in network industries where standards are important.

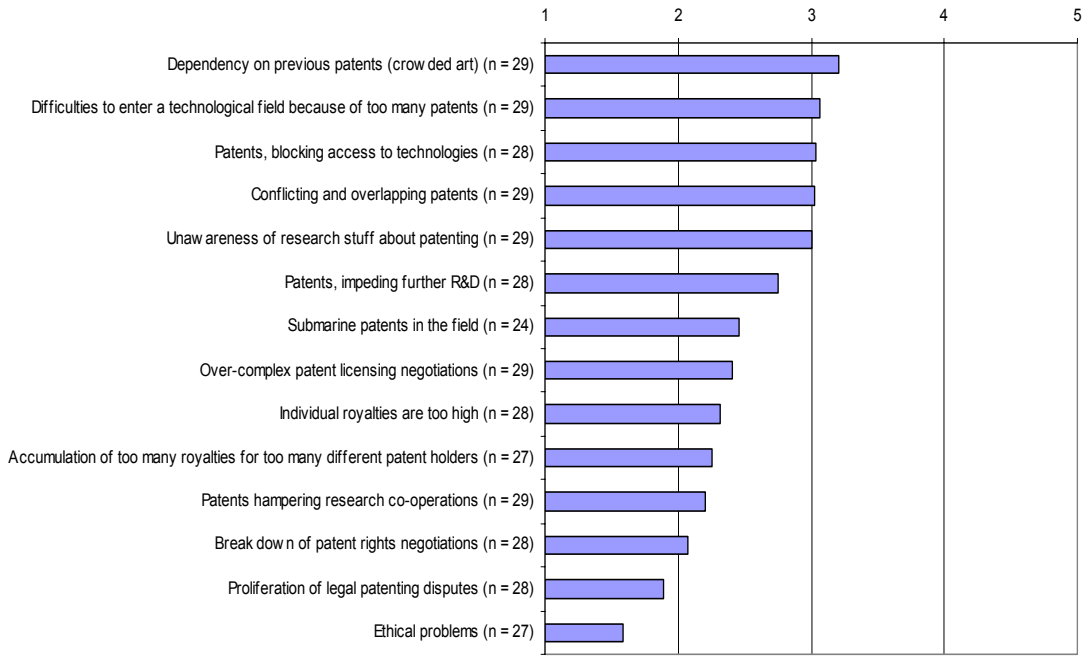
An example of serious anti-trust problems caused by a patent is the Myriad BRCA1 patent which combines a patent blocking situation with an aggressive licensing strategy. The patent held by Myriad Genetics protects the isolated gene as such (chemical molecule) and the corresponding protein and it includes the imaginable future therapeutic uses of the BRCA1 gene. The patent is broad and dominant, since it implies that any other patent application filed for a different use of BRCA1 is dependent on the patent held by Myriad Genetics. Aside from the ethical issues involved, critics are worried that in Europe such patents could create a monopoly in the European Union for the company following the example granting similar patents in the United States. This case and similar problems in the software area have led to an initiative to promote 'open models of innovation' that don't rely on patents and where knowledge is freely available (see the initiative by leading scientists with the World Intellectual Property Organization to promote innovation models without intellectual property protection, Nature 424, 118 (10 July 2003)).

Previous studies (Straus, 2002 and Cohen et al., 2002) confirmed that patents on research tools are rarely enforced and that in general firms do not pursue public research bodies for infringement. It is rare for research projects to be halted due to patent issues. Most of the time 'working solutions' are found. The situation looks different for reach through claims where patents on research tools are the legal ground for royalty claims on products found with the help of that research tool. At an OECD workshop (OECD 2002) reach-through claims together with an unclear situation concerning a research exemption were perceived as a source of commercial uncertainty with a strong need for clarification. With DNA patents, it is the long-term risk of inhibiting an area of science which is still in its infancy that might not justify speculative protection even though the patents allow certain innovations to be brought more rapidly to the market in the short term.

8.2 Problems perceived in Switzerland

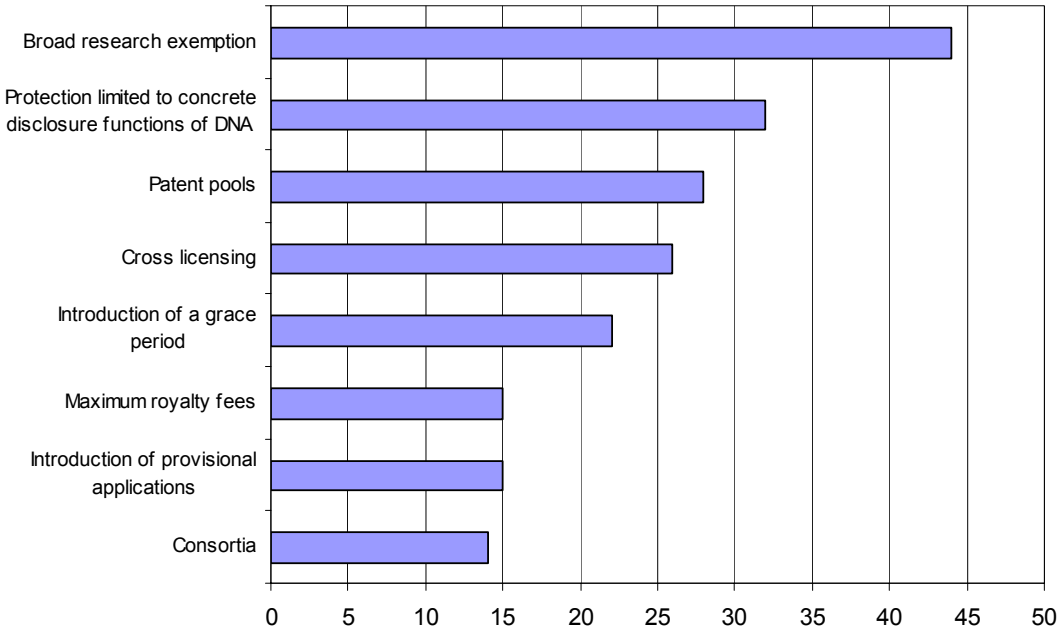
A first look at the results in Figure 34 shows that the biggest problems are the dependencies on previous patents (crowded art), access to certain technologies due to patents and difficulties entering certain technological fields because of too many patents. Research institutes mentioned that the lack of awareness regarding patenting among their research staff (value of 4 in the scale) is a serious problem. Large companies experience the difficulties mentioned more severely than small companies which generally perceive only the dependency on previous patents and difficulties entering a technological field due to too many patents to be problematic. However, one group of small companies disagrees with most of the DNA patenting shortcomings mentioned (indicated by value levels between 4 and 5 on the scale). Cluster analysis shows that this group of participants perceives all of the difficulties mentioned to an extreme extent. Whereas another group, mainly research institutes, have a problem with the unawareness of their research staff as well as with too high licensing fees in general.

Figure 34 - Swiss survey: extent of experience of problems with DNA patents (1=never, 5=very often)



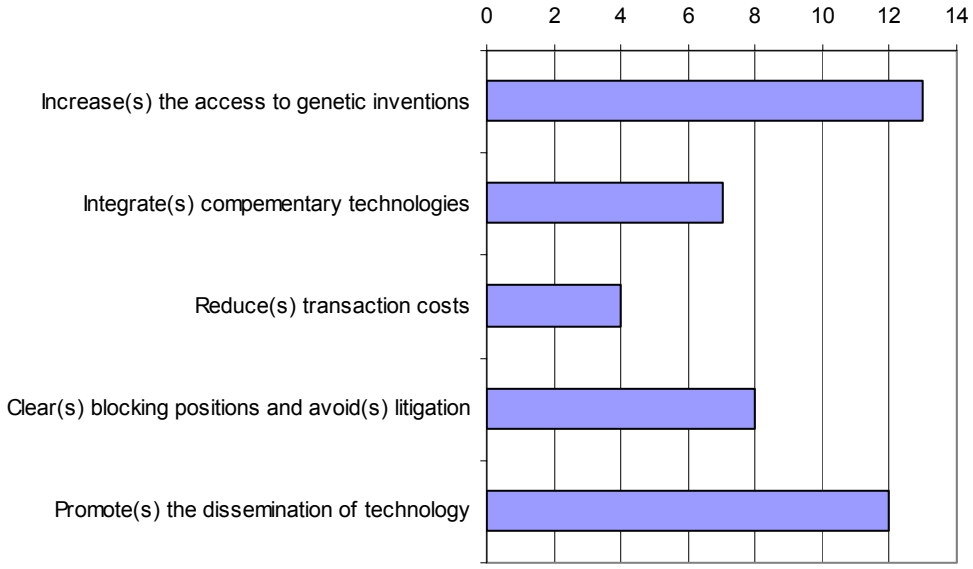
The questionnaire proposed a variety of remedies and asked the participants to assess the remedies based on their experience as to how far they were increasing access to genetic inventions, integrating complementary technologies, reducing transaction costs, clearing blocking positions and avoiding litigation, and promoting the dissemination of technologies. All these remedies try to reduce transaction costs and to provide freedom to operate with proprietary biotechnology. Figure 35 shows the counts of how many times each remedy was mentioned as efficient. It shows clearly that the participants in the survey trust in a broad research exemption and protection that is limited to concrete disclosure functions of DNA. The low enthusiasm for patent pools, consortia and cross licensing is partly explained by the low level of experience companies have with these tools (Annex 23).

Figure 35 - Swiss survey: remedies (named as many times as effectively to ...)



An OECD report (2002) found that most OECD countries operate with a formal or informal research exemption that works reasonably well in most cases. Nevertheless, the transition between 'research' and 'commercial use' and subsequent requirements for licensing agreements needs to be clarified. Unclear definitions of exemptions could have a chilling effect on the progress of basic science.

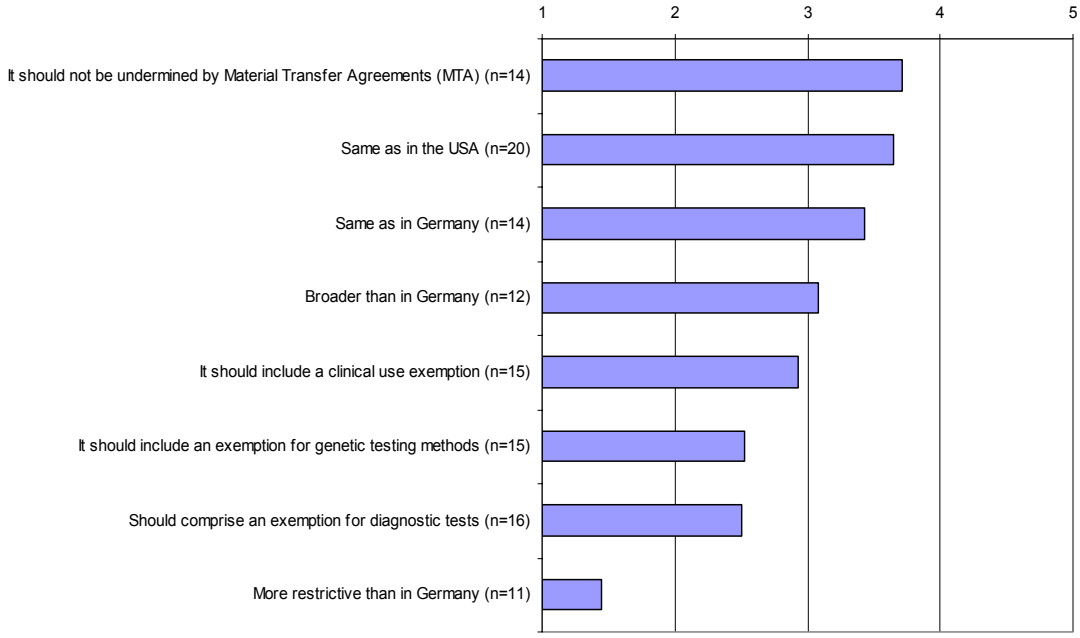
Figure 36 - Swiss survey: broad research exemption (named as many times as effectively to …)



In comparison to other remedies, the introduction of a broad research exemption is believed to be relatively beneficial. Consequently, in the follow-up questionnaire the

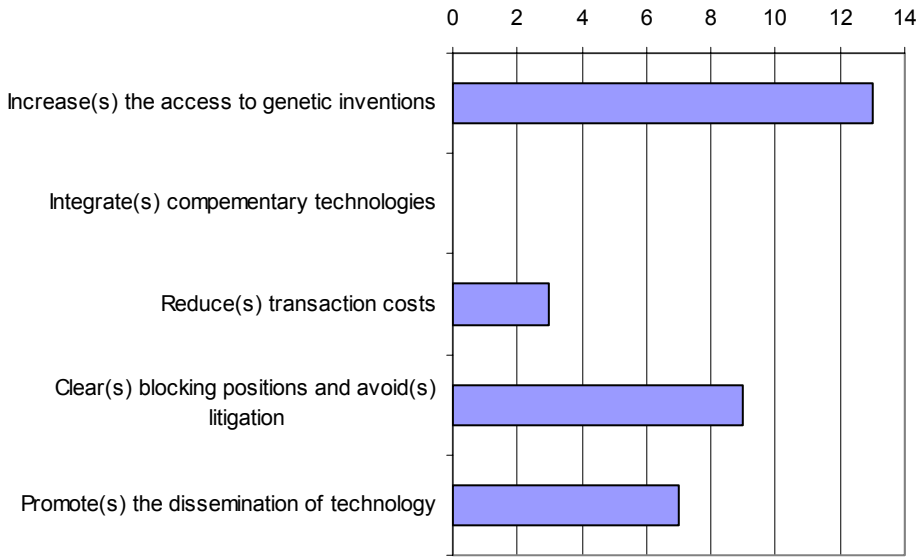
survey participants were asked how they would like to see a research exemption actually be implemented in Switzerland. Figure 37 shows that any research exemption should not be undermined by Material Transfer Agreements, that the orientation of its design should be the United States model and the German version of the research exemption. It was also thought that a research exemption should not be more restrictive than in Germany and that specific exemptions for genetic testing methods or diagnostic tests are of great importance.

Figure 37 - Swiss survey: how would you like to see a research exemption actually implemented in Switzerland? (1=not at all, 5=very much)



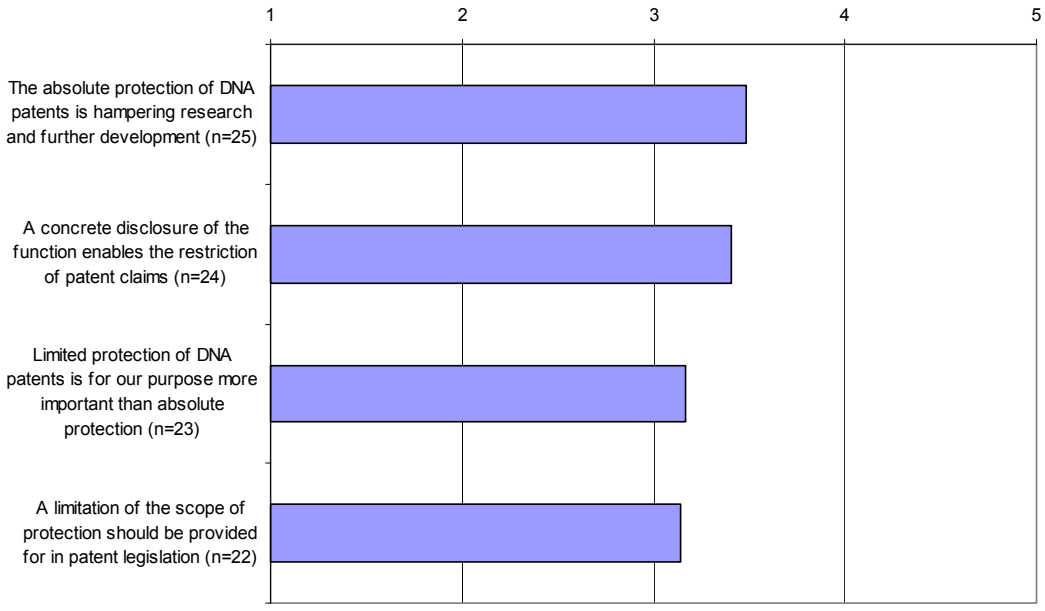
Research institutes emphasize the importance of a research exemption not being undermined by Material transfer Agreements (Annex 15). Small companies favour the model of the USA, over the German model. Big companies prefer a research exemption which is even broader than the German one (Annex 24).

Figure 38 - Swiss survey: protection limited to concrete disclosure functions of DNA (named as many times as effectively to …)



Also the possibility of limiting the protection of DNA patents to concrete disclosed functions of the DNA was welcomed in the first questionnaire. This is particularly relevant for avoiding the patenting of discoveries. In the follow-up questionnaire, participants were asked to assess the possibilities of an actual implementation of such a regulation in Switzerland. Figure 39 shows that all measures were welcomed in general. An absolute protection of DNA would hamper research and further development and only the concrete disclosure of the function of DNA patents would enable the restriction of too broad patent claims.

Figure 39 - Swiss survey: concrete disclosed functions of DNA. How do you assess the actual implementation of such a regulation for Switzerland? (1=no agreement, 5=total agreement)



Research institutes do not believe that patent legislation should provide a limitation of the scope of protection but they believe that a limited scope of DNA patents is more important than an absolute protection (annex 16). Only companies with more than 250 employees are hesitant about including a limitation of the scope of protection in the patent legislation; they also do not believe that a limited scope of DNA patents is more important than an absolute protection (Annex 17).

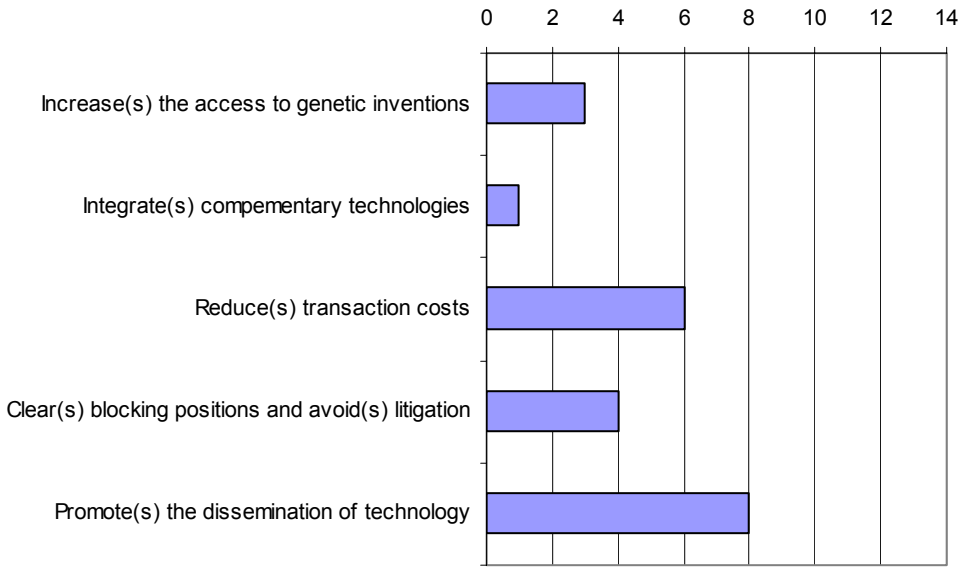
Another remedy to be taken into consideration is the introduction of a general grace period. The novelty requirement under the first to invent system in the United States requires that an invention must not have been in public use or sale or patented or described in a printed publication for one year before the US filing date (35 USC 102 (b)). The assignee is provided with a period of grace of one year. A general grace period is a specific period of time preceding the filing of a patent application during which disclosure by any means (in writing, orally, by use, on exhibitions, etc.) of the invention for which the patent application is filed by the inventor or his successor in title do not constitute prior art with respect to the patent application at hand (Straus, 2000).

A grace period provides the inventor with time for consideration and gives time to evaluate market possibilities. This is in particular in the interest of inventors at universities, where frequently publications are considered to be more important than patent applications. Academics are still relatively unfamiliar with the patent system and they are not always aware of the economic consequences of their behaviour. Consequently, the difficulty of universities might be interpreted as an internal educational task of how to create adequate intellectual property awareness.

More than 30 states have introduced a grace period into their patent laws. On the one hand, inventors in countries without a general grace period are put into comparative disadvantage. This is a major reason in favour of a general grace period in Europe. On the other hand, a general grace period receives a lot of criticism in particular from industry (Galama, 2000). A grace period would raise legal uncertainty for third parties. Inventors making use of the grace period might also run into difficulties when they apply for a patent in countries where no general grace period is in place. The patent system puts others than the inventor into a period of 18 months of uncertainty and a period of grace would add another 6-12 months. This could have effects on the state-of-the-art assessments of technology since not yet disclosed, underlying patent application can destroy novelty.

A survey of the European Commission (2002a) showed that only a very small fraction of researchers and organisations actually experience considerable delay in publication of research results that are the subject of a patent application. In this study, academia favours the grace period as the most important measure to minimise delays with scientific publications. Large industry on the contrary is strictly against a grace period but would favour the introduction of a provisional application.

Figure 40 - Swiss survey: introduction of a grace period (grace period named as many times effectively to …)



The participants of the Swiss sample are not in favour of a grace period (Figure 40) in Switzerland, which is why the issue was investigated more detailed in the follow-up questionnaire. The participants were asked about their particular reasons against a grace period. All the reasons listed in the questionnaire were confirmed to be relevant by the participants (Figure 41).

Figure 41 - Swiss survey: reasons against a grace period (1=no agreement, 5=total agreement)

The participants confirmed, that in their perception (1) a grace period creates legal uncertainty for third parties; (2) only an introduction at the international level would be useful; (3) a grace period would create a misleading perception of security; and (4) it would actually not be necessary when people are adequately informed about the patent system. Private companies, in particular the bigger companies amongst them, believe that only an introduction of a grace period at an international level would be useful (see Annex 18 and 19). Big companies do not believe that the concept of a grace period is poorly defined, but think that it creates a misleading perception of security.

9. Genetic Testing

9.1 Description of the Technology

Genetic tests use a variety of laboratory techniques to determine if a person has a genetic condition or disease or is likely to get the disease. Individuals may wish to be tested if:

- There is a family history of one specific disease;
- They show symptoms of a genetic disorder;
- They are concerned about passing on a genetic problem to their children.

These tests focus on the analysis of the patient's DNA (or sometimes RNA) in order to detect heritable, disease-related genotypes for clinical purposes. Prenatal, newborn and carrier screening, as well as testing in high-risk families, are included. Genetic tests include techniques to examine genes or markers near the genes. Direct testing for diseases such as cystic fibrosis and sickle cell anaemia come from an analysis of an individual's specific genes. A technique called linkage analysis, or indirect testing, is used when the gene cannot be directly identified but can be located within a specific region of a chromosome. This testing requires additional DNA from an affected family member for comparison. Because each person's DNA is unique (except for identical twins), genetic tests can also be used for individual identification ("DNA fingerprinting").

Genetic testing is a complex process, and the results depend both on reliable laboratory procedures and accurate interpretation of results. Tests also vary in sensitivity, that is, their ability to detect mutations or to detect all patients who have or will get the disease. Interpretation of test results is often complex even for trained physicians and other health care specialists. When interpreting the results of any genetic test, one must take into account the probability of false positive or false negative test results. Special training is required to be able to analyze and convey information about genetic testing to affected individuals and their families.

Genetic testing involves the determination of whether a particular DNA sequence is present or absent in a patient's sample. In some cases, tests are designed to determine the presence or absence of known mutations (mutation testing) while in other cases the sample is screened for any deviation from the normal sequence (mutation scanning). There exist a large number of approaches for both mutation testing and mutation scanning. The situation is further complicated by the existence of many different types of genetic mutation (point mutations, deletions large and small, gene rearrangements, duplications, triplet repeat expansions) each of which may require different testing or scanning technologies.

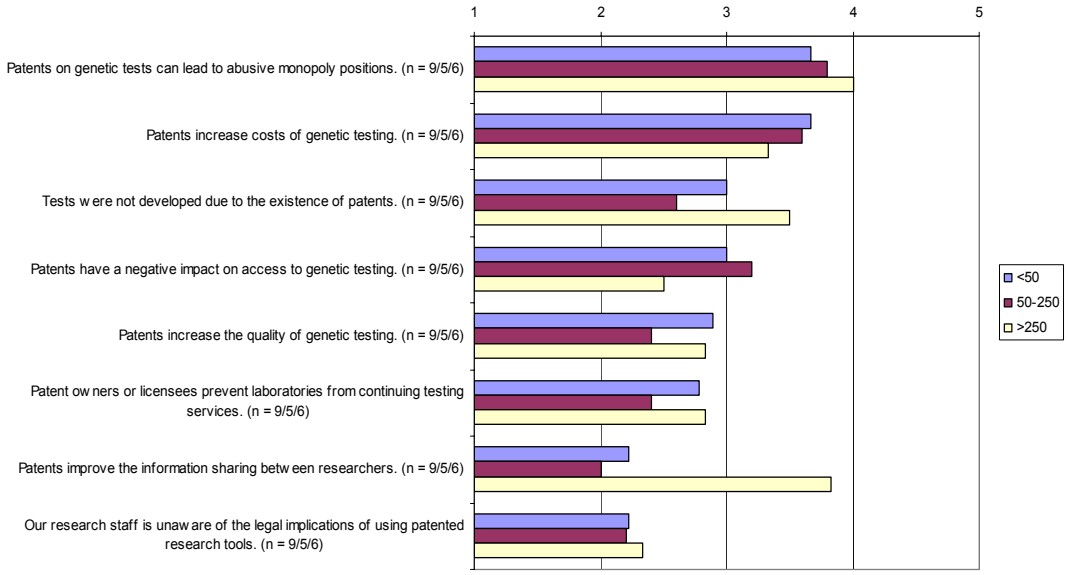
9.2 Genetic testing and patenting

Participants in the survey were asked to rate, according to their experience, their agreement with the statements with respect to genetic testing in Figure 42. Most participants confirmed that patenting can lead to abusive monopoly positions as well as that patents increase the costs of genetic testing. Some tests were not developed due to the existence of patents.

Research institutes have problems with most of the issues mentioned in Figure 42. They particularly have problems with patent owners and the fact that certain tests are not developed due to the existence of patents. Figure 42 shows that big companies perceive most of the problems of patents for genetic testing methods. It is important to see that several small firms are in the same position as big companies and perceive all the mentioned difficulties.

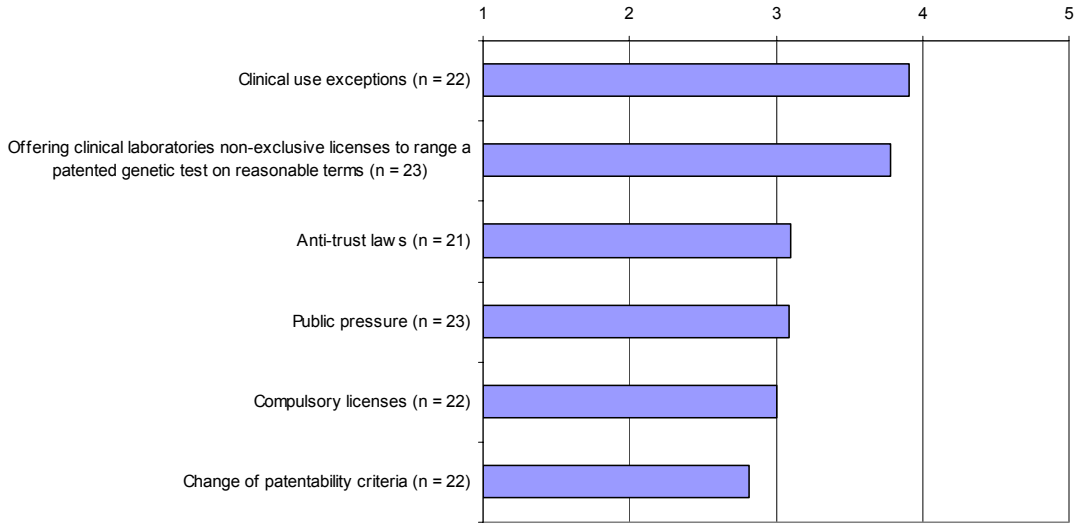
A cluster analysis shows that one group sees only the negative influences of patents, while another group also sees the advantages of patents such as the improvement of the quality of genetic testing. Patents can also have positive effects on the performance of genetic testing methods. First, developing methods of genetic testing on existing patents can reduce the development costs tremendously. Secondly, patents, similar to standards, increase the testing quality.

Figure 42 - Swiss survey: extent of agreement with statements on patents in the field of genetic testing (1=very low, 5=very high), only companies



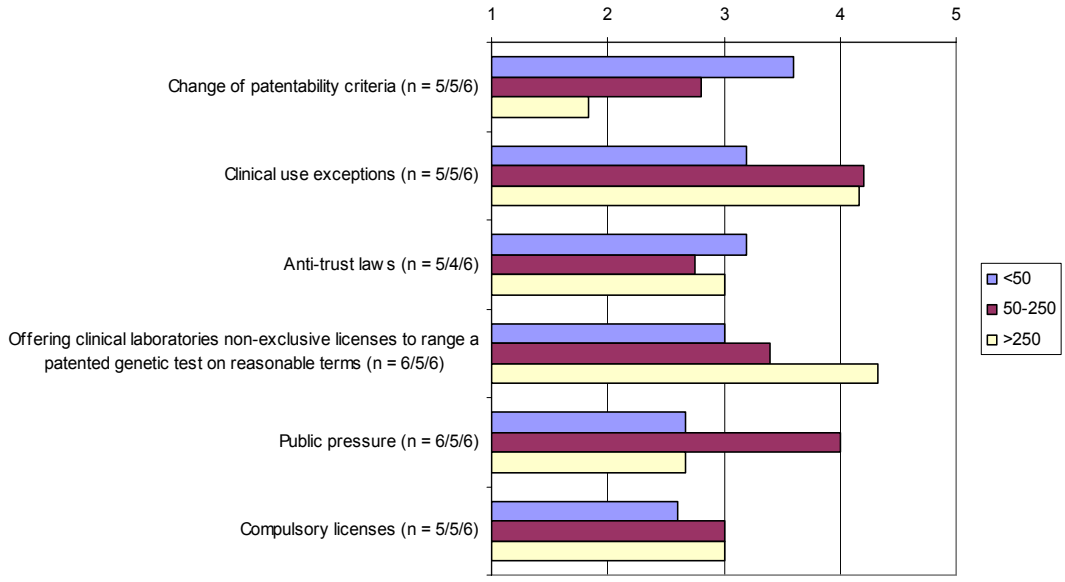
Various remedies to overcome these problems were listed in the Swiss survey: compulsory licensing, the use of anti-trust law, clinical use exemption, change of the patentability criteria, public pressure and offering clinical laboratories on reasonable terms non-exclusive licenses. Figure 43 shows how these remedies were rated by the survey participants.

Figure 43 - Swiss survey: efficacy of remedies regarding patents in the field of genetic testing (1=very low, 5=very high)



Clinical use exemption and offering clinical laboratories non-exclusive licenses for a patented genetic test on reasonable terms are overall evaluated to be efficient remedies helping to overcome the above mentioned difficulties. Research institutes welcome all the mentioned remedies (Annex 20). A more detailed picture can be revealed by looking at Figure 44.

Figure 44 - Swiss survey: efficacy of remedies regarding patents in the field of genetic testing (1=very low, 5=very high), only companies



Big companies are very much in favour of granting non-exclusive licenses to clinical laboratories for a patented genetic test on reasonable terms and they also welcome a clinical use exemption. They are against the use of anti-trust law and a change of the patentability criteria in order to overcome difficulties with patents and methods of genetic testing. Small companies, however, welcome both the use of anti-trust law

and a change of the patentability criteria. Cluster analysis of the sample shows that there is a group of participants that welcomes a more ‘radical solution’ by use of public pressure and a change of the patentability criteria. Another , bigger group trusts in licensing and favours compulsory licenses and non-exclusive licenses to clinical laboratories. A third group relies on the clinical use exception.

10. Summary

1. Survey participants confirm that the patent system is an important incentive for investment in research and development in the field of biotechnology (Figure 19).
2. Patents and licenses for biotechnological inventions are considered an important incentive to stimulate research, knowledge flows and the entry of new technologies into markets (Chapter 5.1 und 5.2).
3. Switzerland files more triadic patent applications (those applications filed at the EPO, the USPTO and the Japanese Patent Office) per inhabitant than any other country in the world (Figure 7). Swiss biotechnology patenting performance indicates that the Swiss biotechnology industry is closely linked to other countries, especially the United States. (chapter 4.2).
4. The Swiss biotechnology industry is one of the strongest in Europe (Figure 2). It is a very research-and-development intensive branch (Chapter 4.3, Annex 3 and 4) with high growth rates (Figure1) and a high potential for innovation (Chapter 2.4). In addition, the industry shows increasing numbers of patent applications. (Figure 8 and Annex 1). Small companies in the sample show the highest potential for innovation in terms of patenting per employee in research and development (Figure 10).
5. For small and medium-sized companies patents are important for the acquisition of venture capital (Figure 14). Research institutes consider patents to be important in order to create licensing income (Figure 26 and Annex 21). Big companies consider patents to be important for all the reasons (except the acquisition of venture capital) mentioned in the survey (Annex 22).
6. Biotechnology companies wish to resolve the unclear legal situation with biotechnological inventions in the European Union and in Switzerland (particularly compared to the USA) and, consequently, welcome the implementation of the European directive on biotechnological inventions in Switzerland (Chapter 7.3 and Figure 31).
7. Patents, secrecy and lead-time advantages, play an important role as protection mechanism for inventions (Figure 19). Big companies and some small and medium-sized companies use patents intensively (chapter 5.4).
8. The level of secrecy for process inventions is much higher than for product inventions. For product inventions, the level of secrecy decreases with company size. For process inventions, secrecy increases with the company size (Figure 22).
9. Main motives to abstain from seeking patent protection are, (1) patents are considered to be too expensive and (2) that patent protection requires the full disclosure of the invention made. Legal insecurity with biotechnology patents in Switzerland, however, does not influence the decision to patent potentially patentable inventions (Figure 23).
10. Only some small companies use the patent system extensively. However, these companies strongly depend on the patent system. They have a very high patenting expertise and also use the patent system strategically (Chapter 5.4 and 6.1).
11. Patent litigation plays a minor role in Switzerland. This is very different from the United States and, partly from the rest of Europe (esp. Germany). As a

consequence, also the costs related to litigation are assessed to be of low importance (Chapter 5.3).

12. The fact that there is only little litigation going on in Switzerland (Figure 15) is, according to the survey participants, not due to the low quality of judges in Switzerland (Figure 16). Nevertheless, some of the big companies find the low experience of some Swiss cantonal judges, due to the disparity among cantons, to be a problem. They believe that patent litigation is better handled outside of Switzerland (in particular in Germany, USA, and UK) (Figure 17, Annex 10). In Switzerland, most patent disputes are either settled amicably or solved in a way of alternative dispute settlement. This applies not only to big companies, but also to small ones (Annex 10).
13. The most important motives for applying for patent protection listed by participants were to (1) protect own technology, (2) prevent competitors' patenting and application activities and (3) improve the technological image of their company (Figure 13).
14. According to the survey participants, strategic patenting is not very common in the Swiss biotechnology industry. Traditional uses of patents (the evaluation of the state-of-the-art in a technological field together with a purely defensive patenting strategy to protect one's own technology), dominate in Switzerland (Figure 24).
15. Mainly big companies look at the patent portfolio of their competitors in a systematic way, with the exception of the few small companies in the sample which are very active in patenting (Figure 25).
16. Companies in the Swiss biotechnology sample have no difficulties in finding licensing partners. Research institutes, however, appear to have some difficulties (Figure 29).
17. With respect to licensing, the survey participants, and in particular research institutes, would welcome a compulsory licensing regulation in those cases where abusive monopoly positions are apparent (Figure 28). Bigger companies hold the view that the accumulation of too many royalty fees could impede effective licensing (Figure 30).
18. Moderate problems involving DNA patents were identified as: (1) strong dependency on previous patents (crowded art); (2) patents that lock access to technologies; and (3) difficulties to enter a technological field because of too many patents and conflicts with overlapping patents (Figure 34). Research institutes notice a low level of expertise of their employees with respect to patenting.
19. Participants consider a broad research exemption and a limitation of the scope of protection of DNA patents to the specific disclosed functions as possible solutions to the Problem with DNA patents (Figure 35, 36 and 39). Survey participants believe that an 'absolute' scope of protection of gene patents would hamper research as well as further development. However, a specific disclosure of the function of DNA patents would enable the restriction of patent claims. Furthermore, the participants agree generally that the scope of protection for DNA patents should be limited (Figure 39). Big companies do not believe that a limitation of the scope of protection is important for their purpose (Annex 17).
20. Almost no companies in the Swiss biotechnology industry show experience with patent pools and/or patent consortia. As a result, companies do not know how to use them. Consequently, they are cautious about collaborating with competitors

(Figure 27). Some (in particular big companies) have, however, some experience with cross-licensing (Chapter 6.2 and Annex 23).

21. There are no serious specific concerns about the European biotechnology directive (Figure 32). Big companies miss, however, a regulation of a research exemption in the directive (Figure 33 and Annex 14).

22. Survey participants raise concerns that the implementation of a research exemption in Switzerland should not be undermined by Material Transfer Agreements (MTA) (Figure 37). Exemptions for genetic testing methods and diagnostic tests, under the concrete form of implementation of a research exemption, are not considered to be important (Figure 37).

23. Participants feel that patents on methods for genetic testing can lead to over-strong monopoly positions. Patents can increase the costs of genetic testing methods - there have been cases where this has led to the non development of new testing methods (Figure 42). However, some companies in the sample perceive that the advantages of patents in the field of genetic testing outweigh these disadvantages. The development of testing methods on the basis of already existing patents reduces research costs and can lead to cheaper follow-up methods of genetic testing. Patents, similar to standards, also function as a guarantee of quality and safety of genetic testing methods. In order to overcome the problems with genetic testing patents, the survey participants suggest that efficient remedies would be clinical use exemption and offering clinical laboratories non-exclusive licenses for to range a patented genetic test on reasonable terms (Figure 43 and 44).

24. Survey participants in general do not believe that the introduction of a grace period would be an efficient remedy to overcome shortcomings with DNA patents (Figure 40). The introduction of a grace period would create legal uncertainties for third parties. A grace period would not be necessary if the public is adequately informed of how the patent system functions (Figure 41). The companies in the sample are of the view that only an introduction of a grace period at the international level would be useful (Annex 18). Effectively, a grace period would create a misleading perception of security (Figure 41).

11. Conclusions

> *'If we did not have a patent system, it would be irresponsible, on the basis of our present knowledge of its economic consequences, to recommend instituting one. But since we have had a patent system for a long time, it would be irresponsible, on the basis of our present knowledge, to recommend abolishing it'. (Machlup 1958)*

Strengthening the patent system is likely to permit more trade in disembodied knowledge; it is likely to facilitate the vertical disintegration of knowledge-based industries and to enable the entry of new firms that possess mainly intangible assets. Strengthening patent law can increase patenting activity and the strategic uses of the patent system. Stronger patent rights should increase innovative performance in biotechnology.

I. (Chapter 10, pts. 1& 2) The survey results could neither confirm the break-down nor a systematic abuse of the existing patent system for biotechnological inventions in the case of Switzerland. The survey findings, however, could confirm that patents are an important factor for innovation in their existing form and that they provide an essential incentive for biotechnological inventions.

II. (Chapter 10, pt. 3) The Swiss biotechnology industry is a globally important player in the life sciences industries. Biotechnology (closely linked with the pharmaceutical industry in Switzerland) is one of the most innovative industries. In view of the life sciences' high potential for future innovation and economic growth, innovation policy in Switzerland should put a special emphasis on the establishment of a prosperous environment in the field of biotechnology which is closely linked with other countries, especially the United States.

III. (Chapter 10, pt. 4) The patent system is an important element of the national innovation system and of innovation policy in Switzerland. Adequately protecting biotechnological inventions with patents is a key factor in industry growth and the ability for research institutes to prosper. Small and medium-sized enterprises show the highest potential for innovation. The survey shows that about half of the small companies are adequately informed about the patent system and its use. The other half, however, are not sufficiently informed and do not use the patent system. Taking the high potential for innovation among small and medium-sized companies into consideration, it becomes clear that adequate measures to inform small and medium-sized enterprises about the patent system and its potential could be very beneficial.

IV. (Chapter 10, pt. 5) The survey findings show that the awareness of the potential of intellectual property at research institutes and universities has risen. Nevertheless, there is a need to continue raising awareness about the management of intellectual property at research institutes and universities. It would be useful to encourage awareness training in the different uses of intellectual property rights during the entire research and innovation process and to raise awareness among academics about the commercial potential of their research in order to encourage entrepreneurship and movement between academia and companies. Moreover, improved collaboration and sharing of know-how between universities with respect to patenting issues would be desirable if universities would like to profit more from licensing income.

V. (Chapter 10, pt. 6) Harmonisation of the legal framework for biotechnological inventions in Europe is welcomed and desired. The ongoing patent law reform in Switzerland should therefore include an adequate consideration of the European directive on biotechnological inventions in Switzerland.

VI. (Chapter 10, pts. 7 & 8) Secrecy and patents are of equal importance to Swiss biotechnology firms and probably a good mix of both is best. Taking the actual regulatory framework in Switzerland into consideration, the balance between patenting, secrecy and lead-time advantages is very much in the hands of the individual company/research institute/university. Patenting, however, cannot be omitted in the intellectual property strategy of biotechnology entities because only patents provide a legally binding form of appropriation. One main justification of a patent system is to disseminate knowledge through disclosure. Only patents can protect the intellectual property and at the same time make the intellectual property available for a broader public use through means of public disclosure. Secrecy, as an alternative to patents, could decrease public welfare by reducing the flow of ideas among firms, thus reducing the overall rate of innovation. Consequently, from a policy point of view, patents are more desirable than secrecy and other alternative protection measures. Patent policies should encourage companies/research institutes/universities to patent rather than to use secrecy.

VII. (Chapter 10, pt. 9) Patent protection has to be available at a reasonable price in conjunction with an effective enforcement system.

VIII. (Chapter 10, pts. 11 & 12) The low degree of patent litigation is mainly not perceived as an indicator of an inefficient litigation system in Switzerland. Nevertheless, big companies complain about the low level of experience of certain cantonal judges in patenting issues. Taking the international character of the Swiss biotechnology sector into consideration, a European solution for the litigation system via the European Patent Litigation Agreement (EPLA) and the establishment of a European patent court is most likely to provide the adequate know-how and expertise as well as an efficient litigation procedure. In addition, the establishment of a national patent court / a European Patent Court incorporating a regional chamber responsible for claims of national character for Switzerland should be taken into consideration.

IX. (Chapter 10, pts. 10, 13, 14 & 15) Property rights in general offer their owners a variety of strategic uses in the market place that no longer conform to the original idea of intellectual property rights as a remedy against market failure. They stimulate innovator's interest in the property rights themselves and in the related payoffs. This growing use of patents as a strategic tool not only highlights the tremendous importance of knowledge ownership in the knowledge-based society, but also emphasizes the need to further develop intellectual property rights protection. Patents appear to provide an incentive to conduct research and development even where they are used strategically. Furthermore, patents, when used strategically, can contribute to the development of information flows. However, strategic uses of patenting are not common in Switzerland. Abuses of the patent system for reasons other than protecting technology in a broader sense (including portfolio analysis etc.) are not a problem in Switzerland and, therefore, need not be a policy concern. In principle, the patent system itself comprises the strategic uses and abuses of patenting. The general use is subject to free competition and the contractual freedom of each party under the constraints of competition law.

Competition law should properly be implemented and enforced, where patenting issues give reason for anti-competitive concerns.

X. (Chapter 10, pts. 16, 17 & 23) In areas where patents cause serious access problems to certain technologies (e.g. in the field of genetic or diagnostic testing), guidelines for good-practice licensing could help to counteract abusive monopoly positions. The Swiss Federal Institute of Intellectual Property is therefore actively participating in the establishment of the OECD 'Best Practice Guidelines for the Licensing of Genetic Invention' (OECD 2003b). In case such guidelines will prove insufficient, more severe policy measures, particularly additional compulsory licensing conditions, would have to be taken into consideration.

XI. (Chapter 10, pts. 18, 19 & 23) In the survey, only a few responses perceived that too much patenting constituted barriers for access to technologies and for further research. According to these respondents, a limitation of the scope of protection of DNA patents coding for proteins should be discussed under the following conditions: the limitation of the scope of these patents should (1) not discriminate the subject matter, and (2) respect international obligations of Switzerland. The definition of a broad research exemption (similar to one in Germany) is considered to be a more efficient strategy to resolve problems of access to those technologies of public interest. A clarification of 'experimental' use would also be helpful. Industry demands to raise the current patent standard to further promote access to next generation genomic research, and as a result to encourage innovation. With regard to problems with DNA patents coding for proteins, facilitating compulsory licensing conditions should be reconsidered wherever feasible. The formulation of non-exclusive licensing agreements could be an efficient strategy to resolve gene patent problems, particularly for publicly funded research.

XII. (Chapter 10, pt. 19) Good intellectual property policy is not necessarily equivalent to long-lasing and broadly scoped intellectual property rights. The policy objective should therefore be good policy not maximal rights. High quality patents fully satisfy the patenting criteria; they provide sufficient disclosure and are guaranteed to be valid. Poor patent quality can lead to a reduction in investment and commercialisation of an innovation. It can slow progress in cumulative technologies and increase the level of rights fragmentation. While increasing the benefits derived from patents, improved patent quality might also increase the probability of litigation. The correct application of patentability criteria would help to increase the quality of patents. Patents which do not comply correctly with the patentability criteria give more cause for competitors to complain. Intuition would, therefore, suggest that poor quality patents encourage infringement and litigation. For small companies using the patent system, patents have an essential value. For biotechnology companies they are often the only asset. Raising patenting standards has to take into consideration that higher costs of the patent system could hurt small companies seriously.

XIII. (Chapter 10, pt. 20 & 23) Patent pools, cross-licensing and patent consortia are hardly known in Switzerland. These strategies help to reduce transaction costs and avoid patent thickets. Cross-licensing is a potentially efficient tool to reduce enforcement costs. A patent clearinghouse along with further development of cross-licensing and the raise in awareness with respect to the high potential of patent pools and patent consortia, could be a 'one stop shop' offering clinical laboratories non-exclusive licenses for genetic testing methods on reasonable terms. Experience from other industries shows that patent pools, cross- licensing and

patent consortia could potentially be very efficient strategies to overcome problems involving patents in the field of genetic inventions. How patent pools, cross-licensing and patent consortia are used should be observed so that an efficient way to implement them in the biotechnology sector can be found.

XIV. (Chapter 10, pt. 22) The use of a broadly defined research exemption should not be undermined by Material Transfer Agreements (MTA). Either an explicit regulation of the binding character of the research exemption or a regulation on the content of MTAs could help in this respect.

XV. (Chapter 10, pt. 24) Considering the international character of biotechnology patenting in Switzerland (see Section 4.2), only the introduction of a grace period at an international level could be appropriate for Switzerland.

12. Literature

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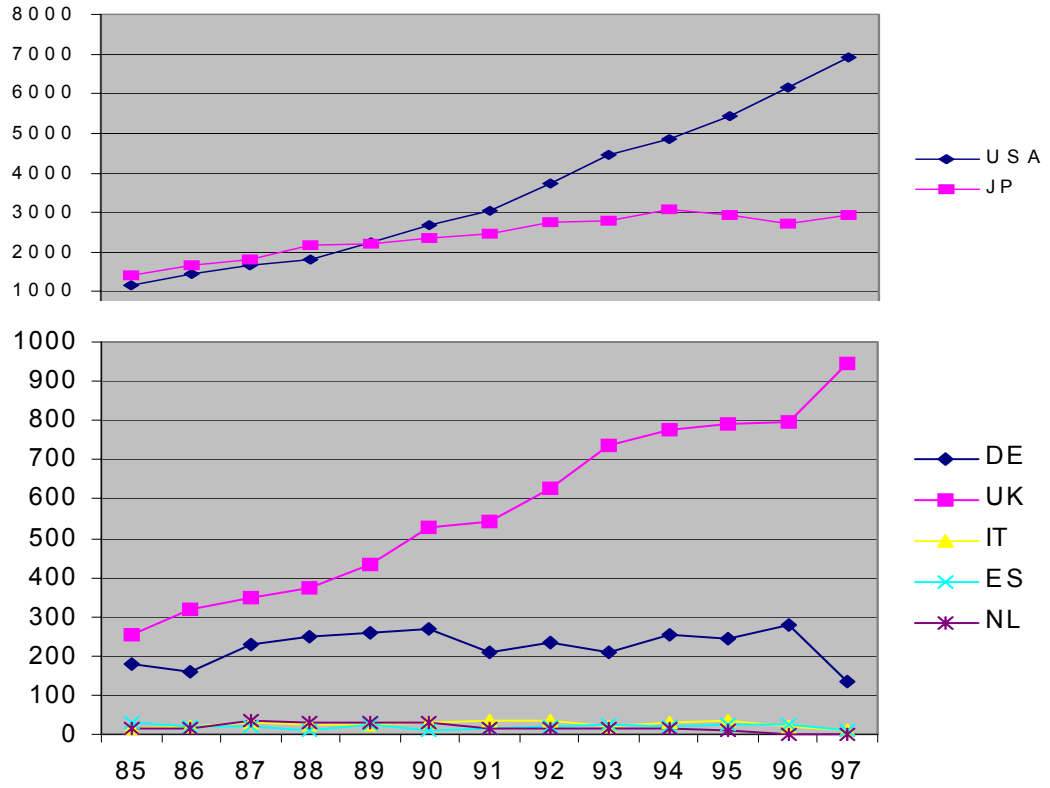
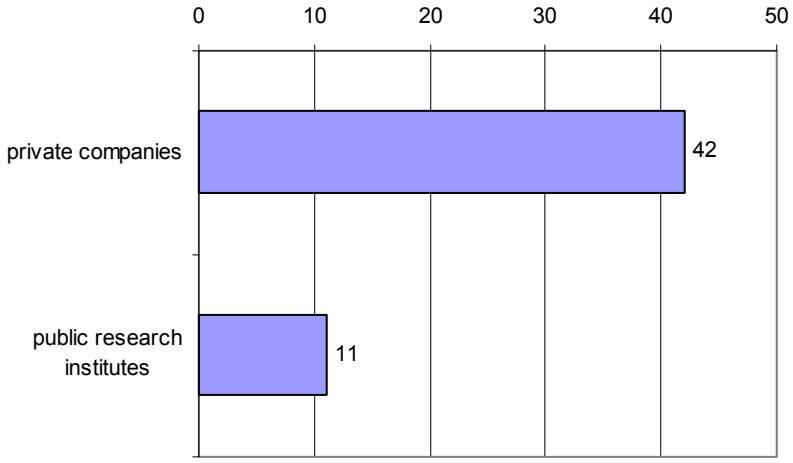
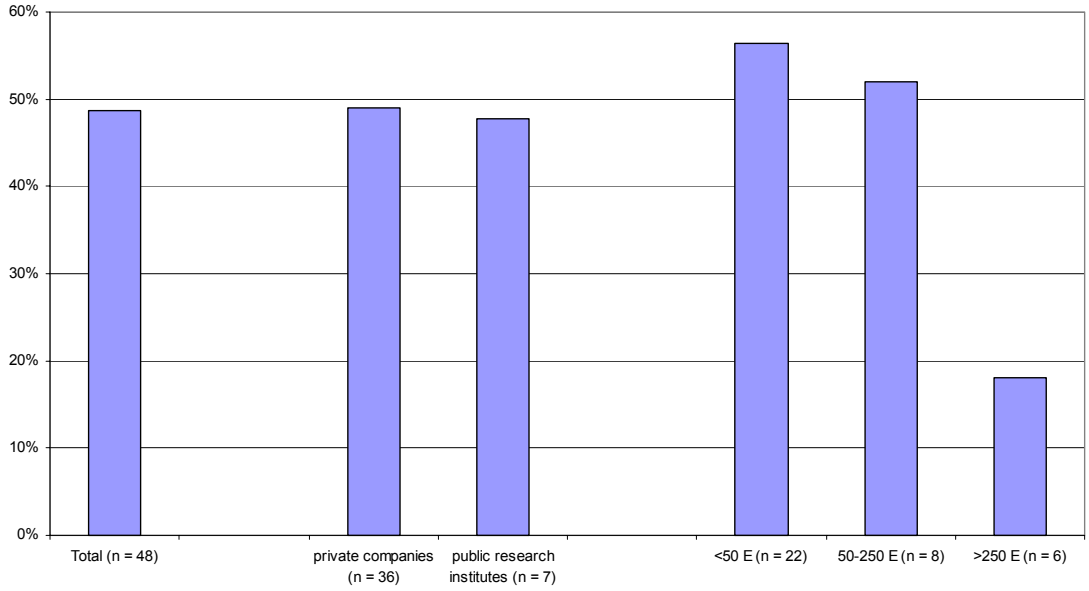
13. Annex 1-24 (graphics)



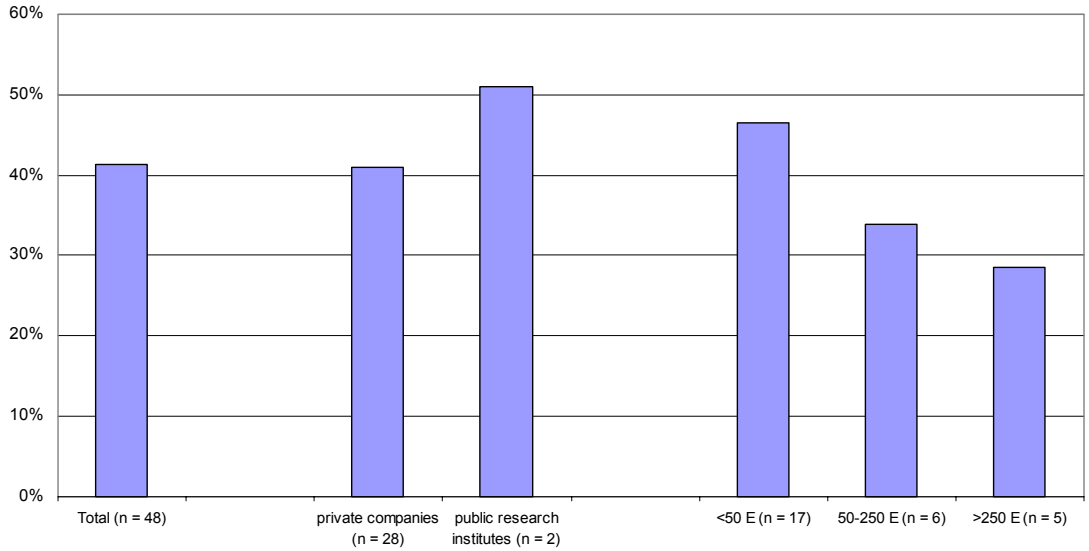
Annex 1 - Priority patent applications in genetic engineering (IPC-class = C12N), source: Derwent World Patents Index



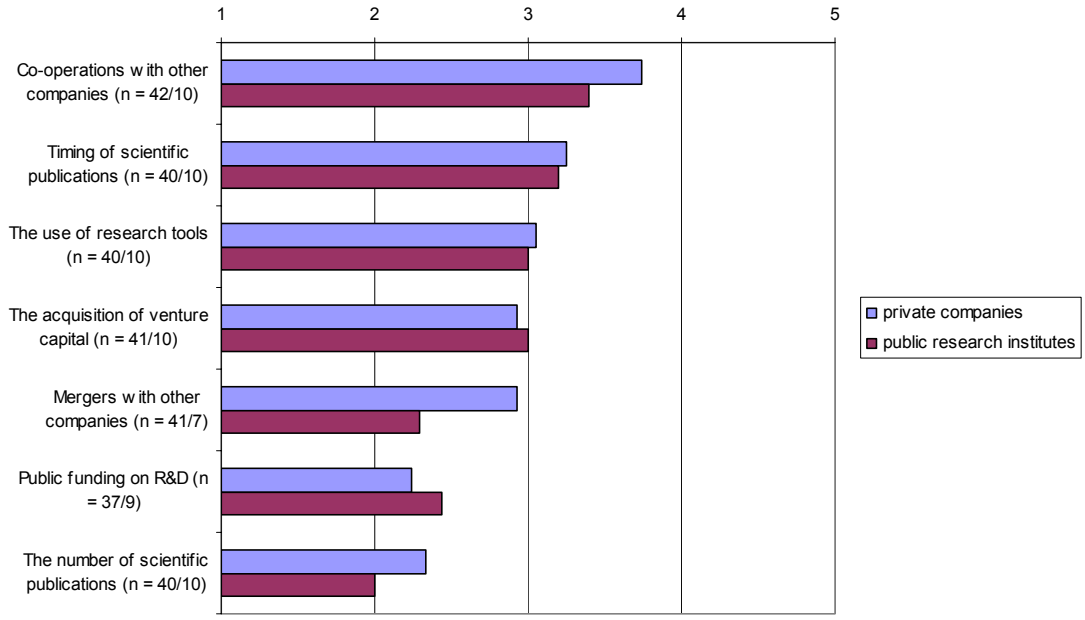
Annex 2 - Swiss survey. Distribution of the sample by public and private institutions



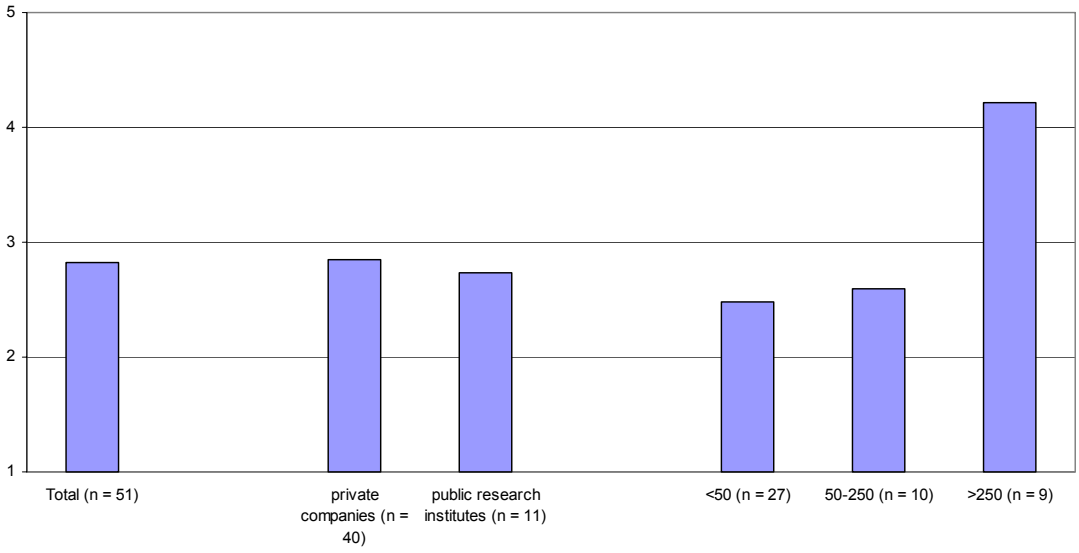
Annex 3 – Swiss survey: distribution of the sample by the percentage of employees in R&D



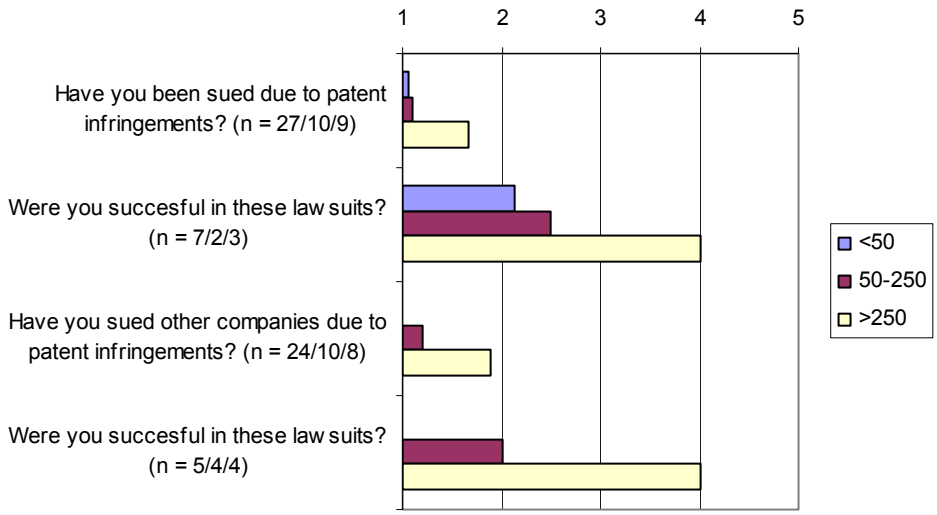
Annex 4 – Swiss survey: Distribution of the sample by the average of R&D expenditure in % of total turnover



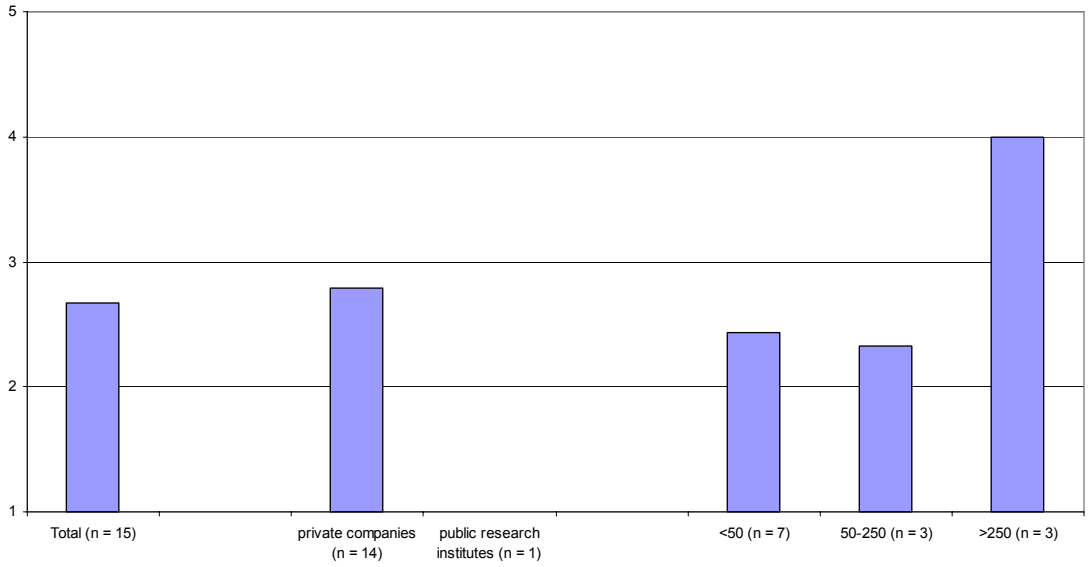
Annex 5 – Swiss survey: Importance of patents in the context of different fields (1=very low, 5=very high)



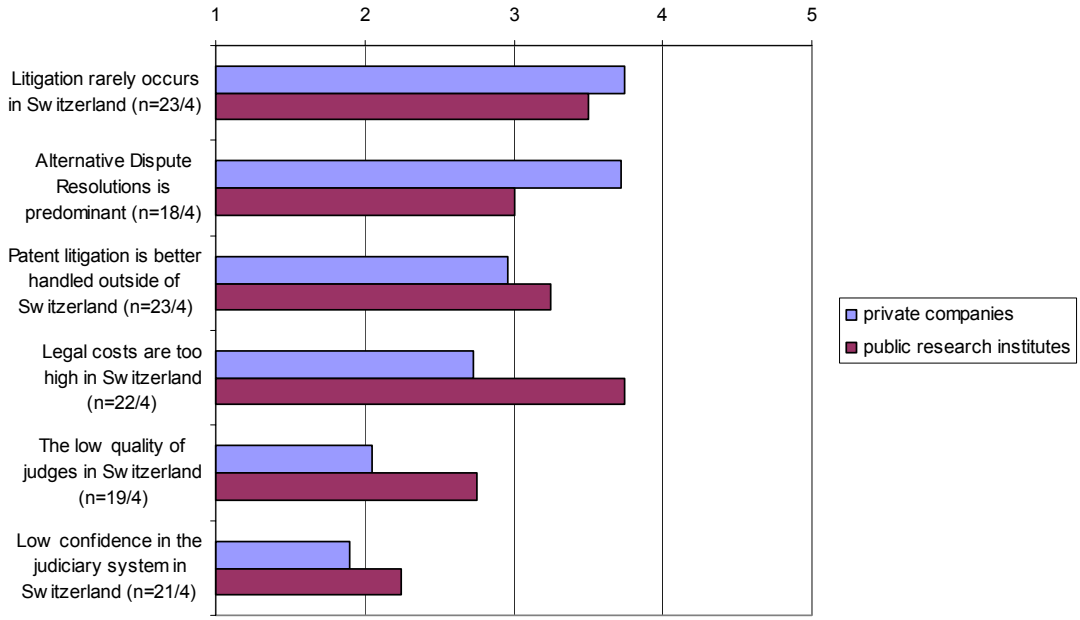
Annex 6 – Swiss survey: Possession of in-house expertise in patent law (1=low, 5=very high)



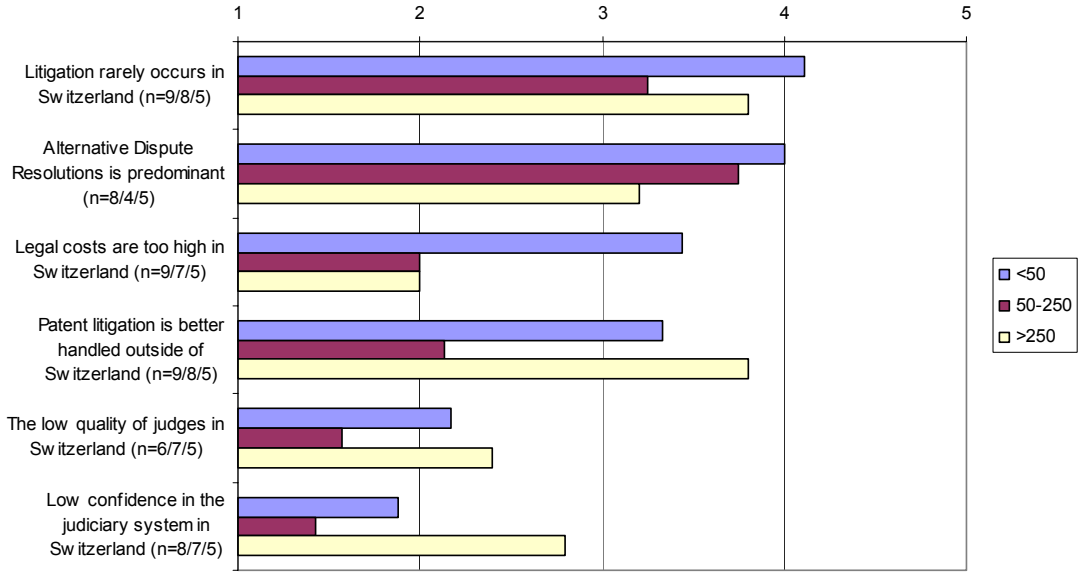
Annex 7 – Swiss survey: legal issues I (1=never, 5=very often)



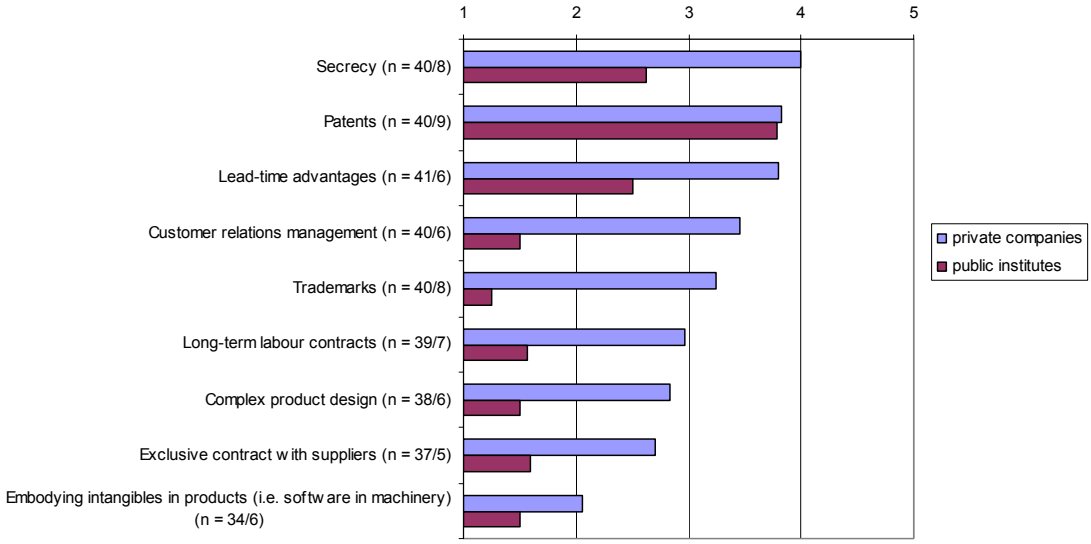
Annex 8 – Swiss survey: legal issues II, were the costs for your company/institute high? (1=never ; 5=very often)



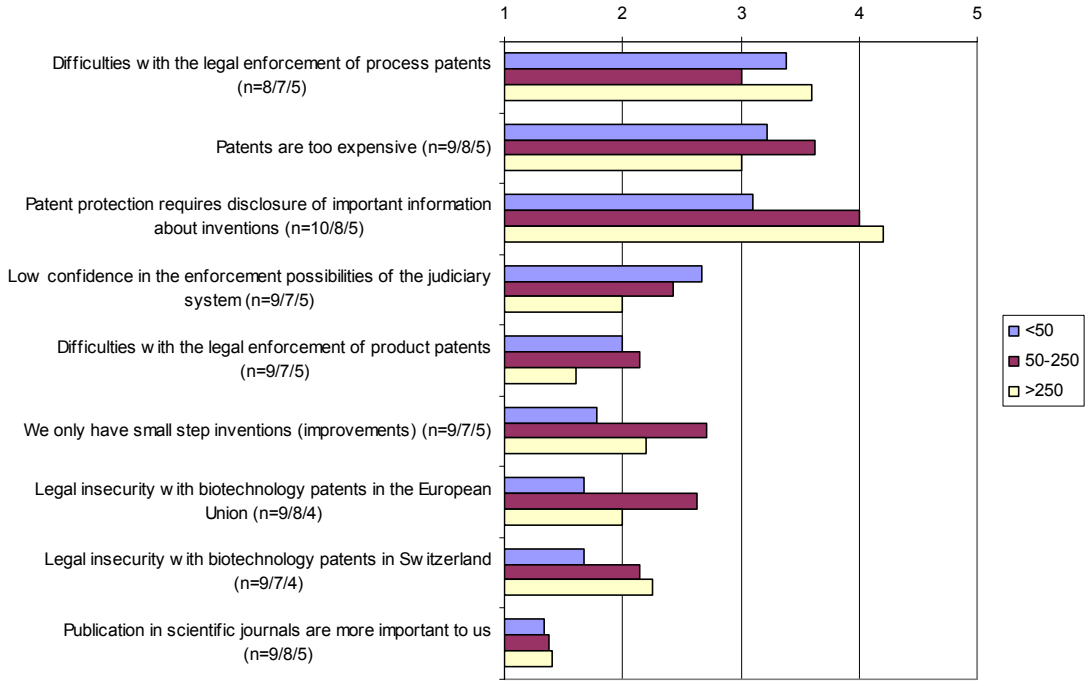
Annex 9 – Swiss survey: reasons for the low number of patent litigations in Switzerland (1=no agreement, 5=total agreement)



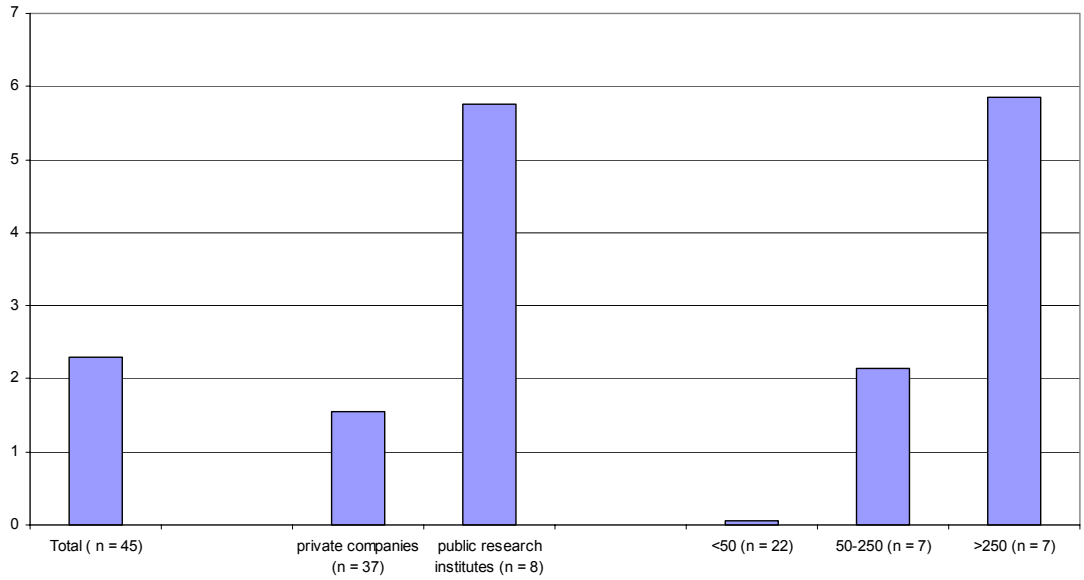
Annex 10 – Swiss survey: reasons for the low number of patent litigations in Switzerland (1=no agreement, 5=total agreement), only companies



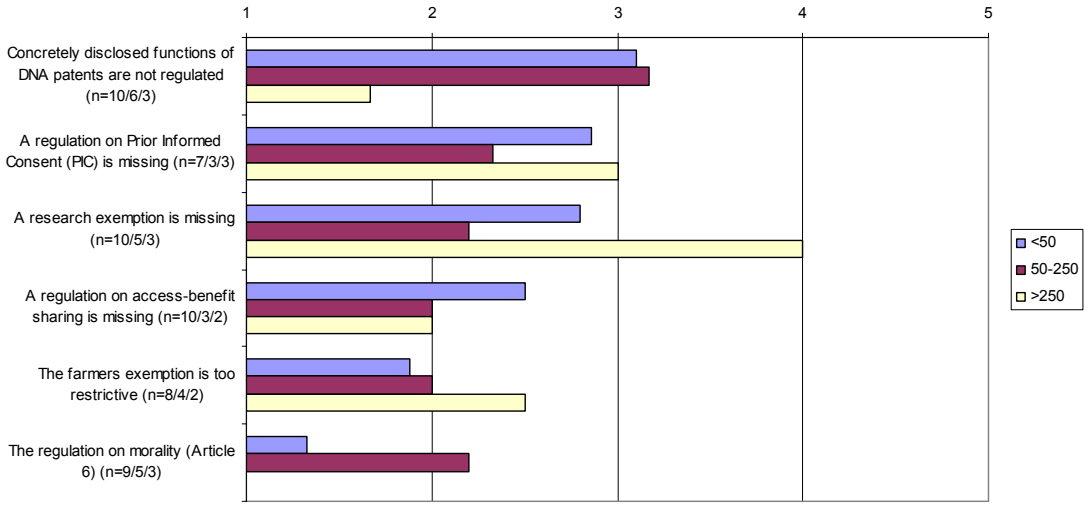
Annex 11 – Swiss survey: Importance of different methods to protect inventions or innovations (1very low, 5=very high)



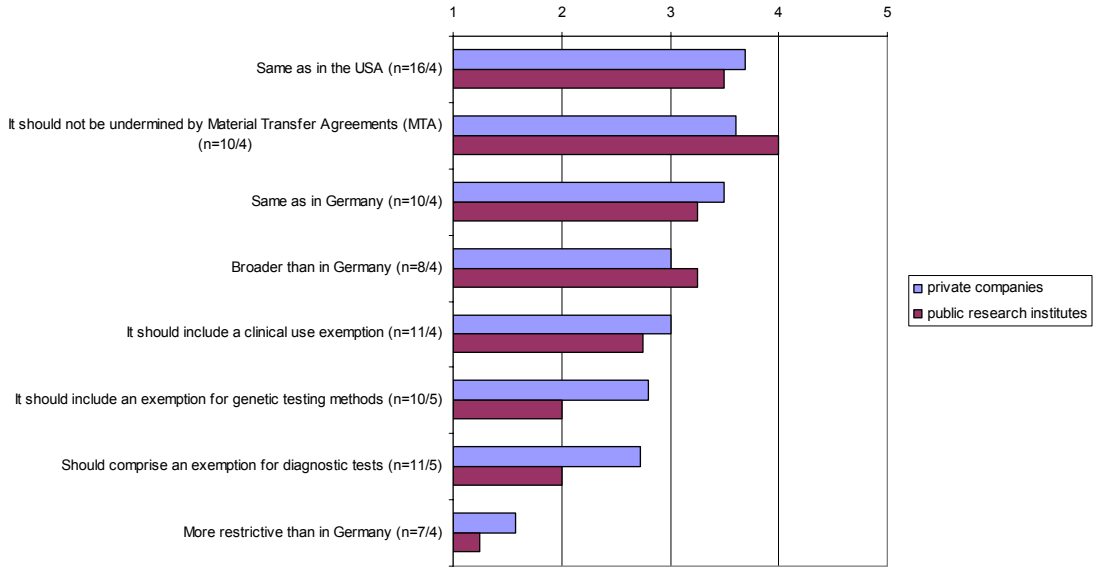
Annex 12 – relevance of motives not to patent potentially patentable inventions (1=not relevant, 5=very relevant), only companies



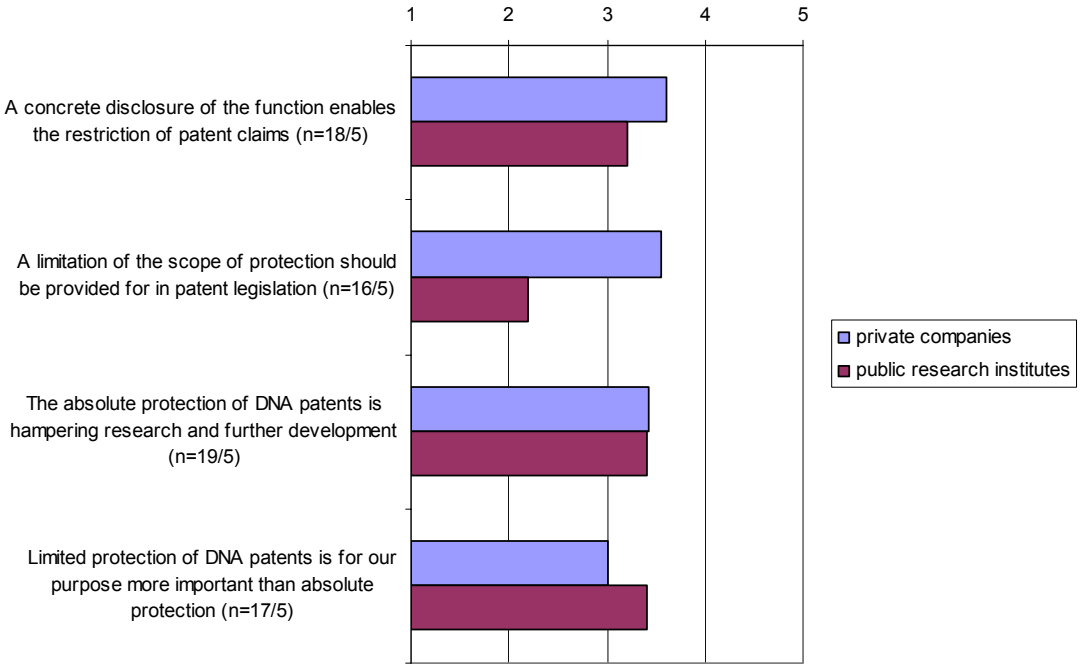
Annex 13 – Swiss survey: number of DNA patent applications



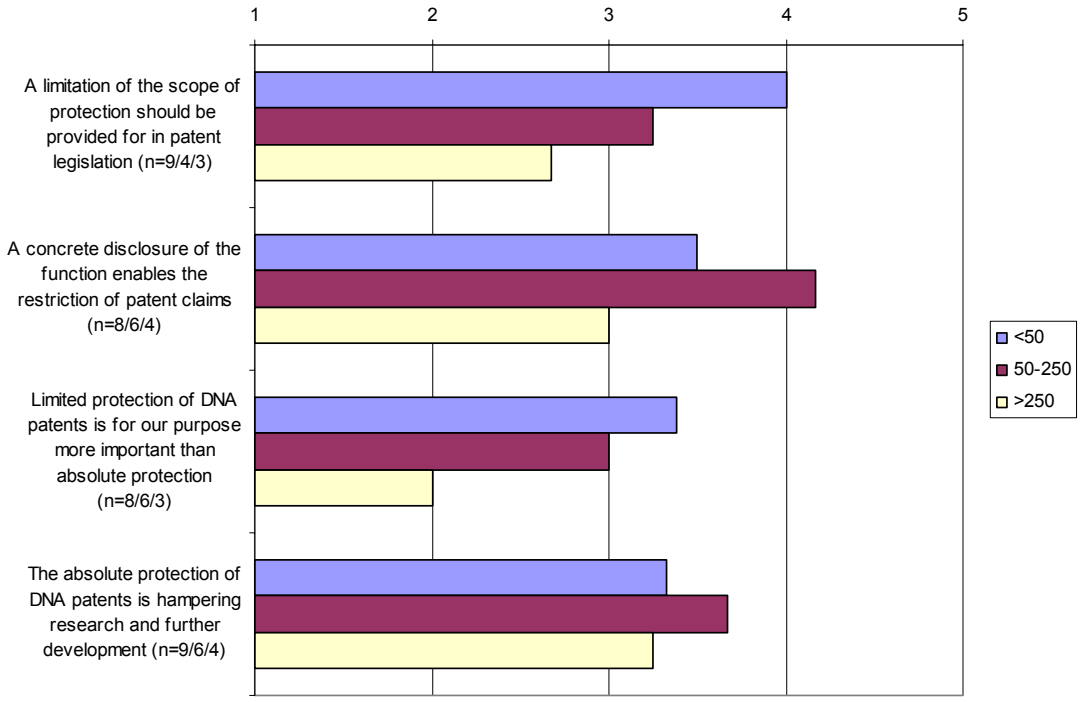
Annex 14 – Swiss survey: Do any of the following regulations of the EU directive on the legal protection of biotechnological inventions concern you? (1=no concerns, 5=many concerns), only companies



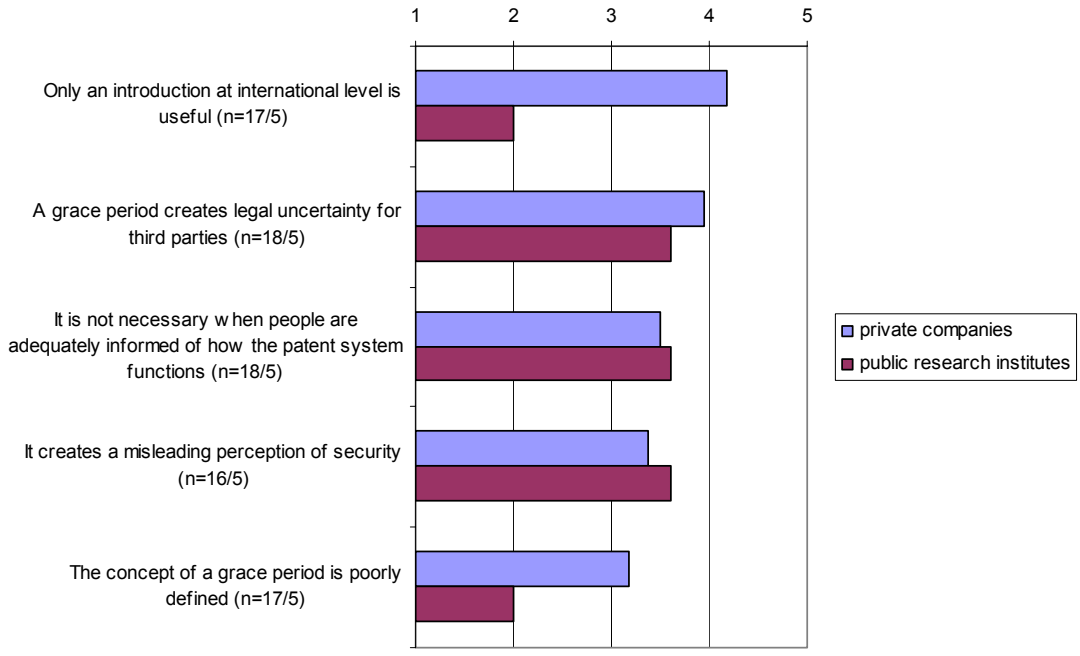
Annex 15 – Swiss survey: How would you like to see a research exemption actually implemented in Switzerland? (1=not at all, 5=very much)



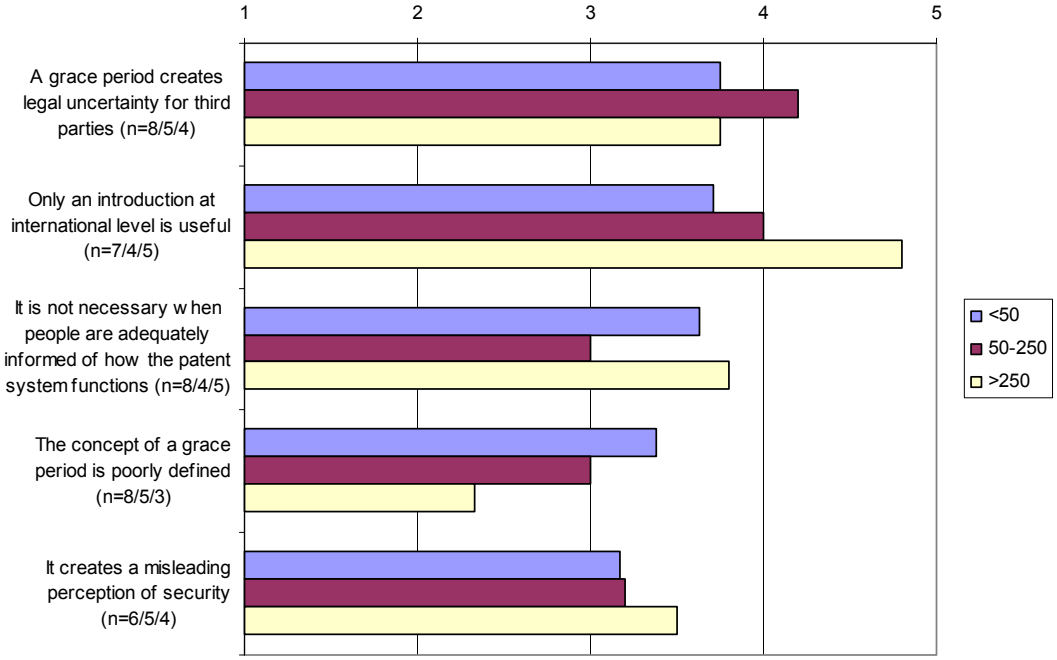
Annex 16 – Swiss survey: Assessment of the actual implementation of limited protection of DNA for Switzerland (1=no agreement, 5=total agreement)



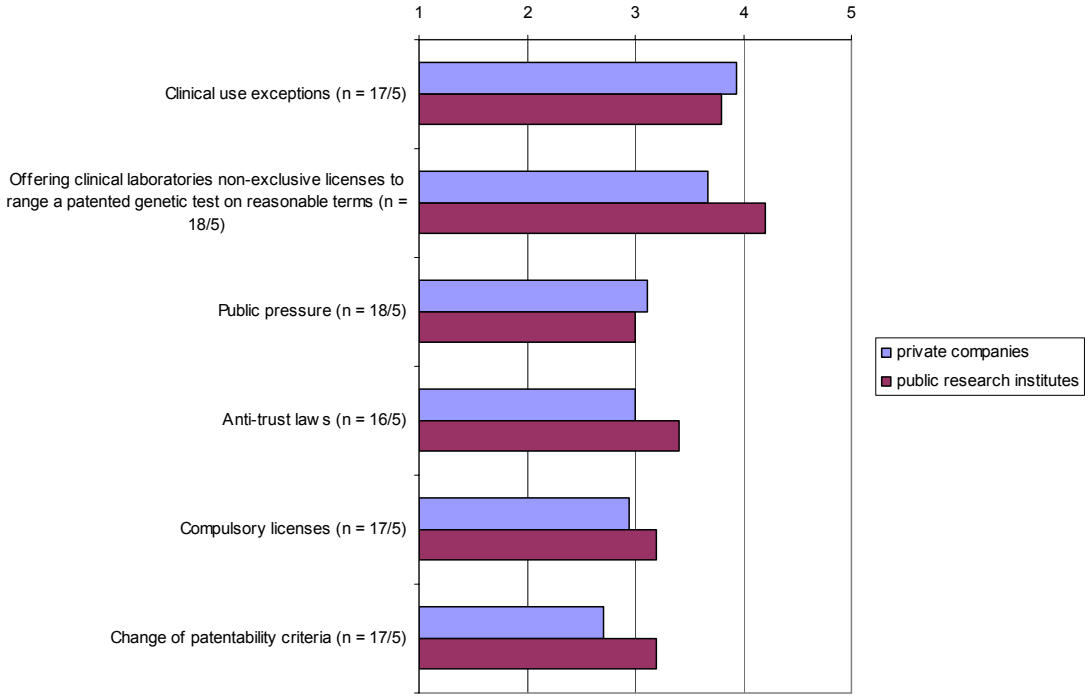
Annex 17 – Swiss survey: Assessment of the actual implementation of limited protection of DNA for Switzerland (1=no agreement, 5=total agreement), only companies



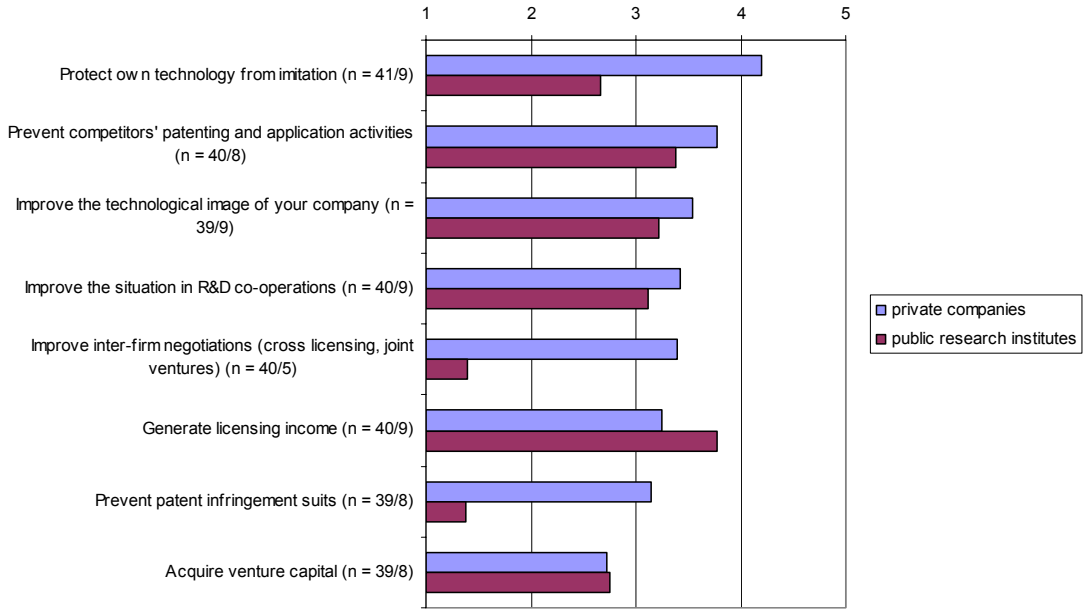
Annex 18 – Swiss survey: Reasons against a grace period (1=no agreement, 5=total agreement)



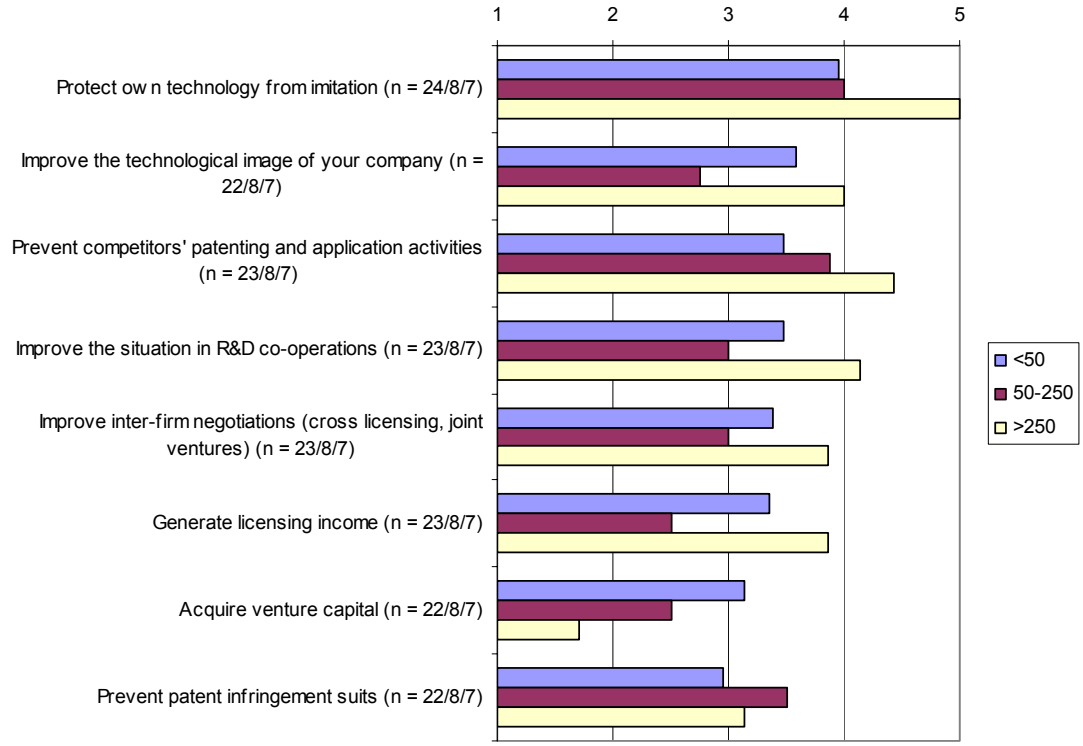
Annex 19 – Swiss survey: Reasons against a grace period (1=no agreement, 5=total agreement), only companies



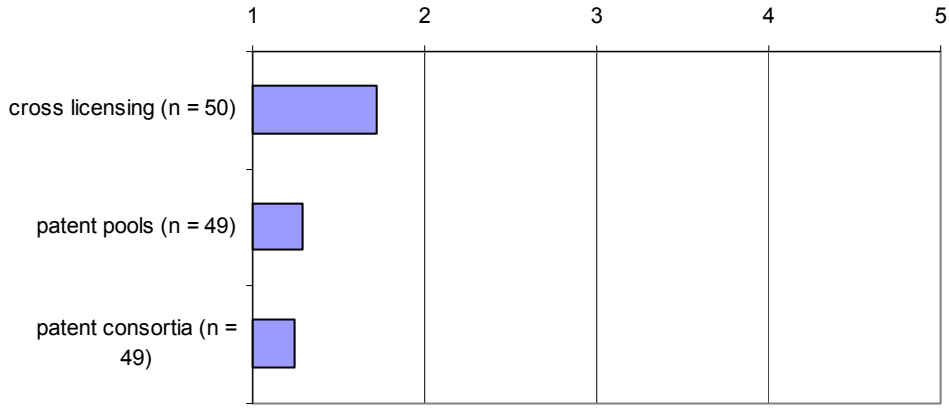
Annex 20 – Swiss survey: Efficacy of remedies regarding patents in the field of genetic testing (1=very low, 5=very high)



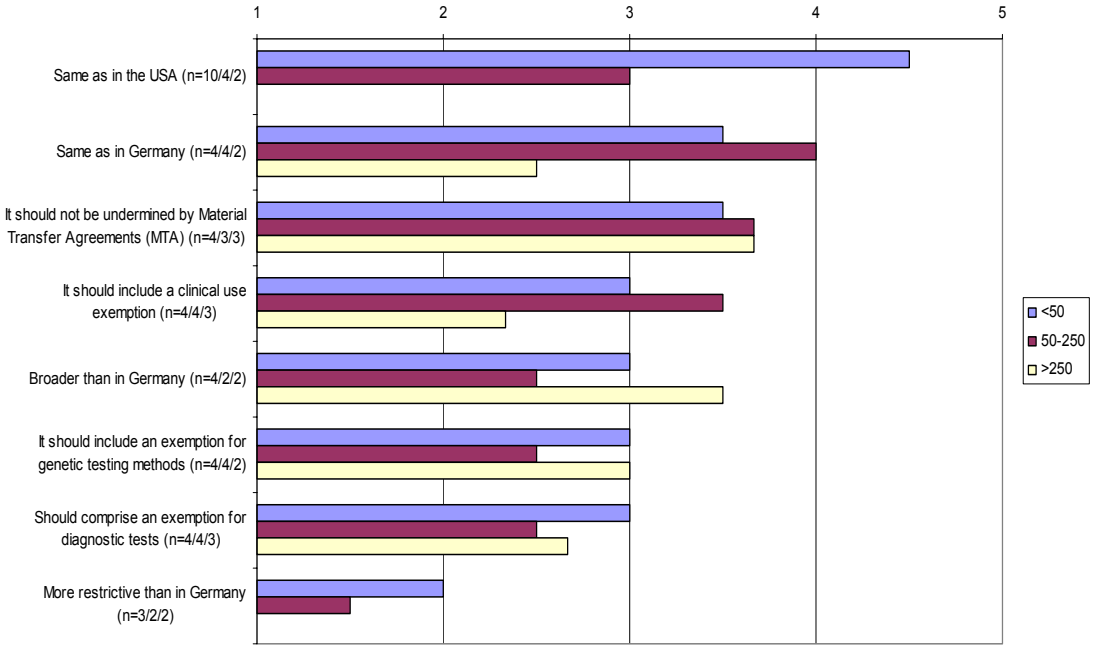
Annex 21 - Swiss survey: Importance of motives to apply for a patent (1=very low, 5=very high)



Annex 22 - Swiss survey: Importance of motives to apply for a patent (1=very low, 5=very high), only companies



Annex 23 – Swiss survey: degree of experience with cross licensing, patent pools and patent consortia (1=never, 5=very often)



Annex 24 – Swiss survey: How would you like to see a research exemption actually implemented in Switzerland? (1=not at all, 5=very much), only companies

14. Annex 25 (questionnaire)

Research and Patenting in Biotechnology

A survey in Switzerland

We would kindly ask you to fill-in the attached questionnaire. It will take only about thirty minutes to complete it. Alternatively, if you prefer, you can fill in an electronic version of the questionnaire, which can be found at:

http://www.ige.ch/E/jurinfo/biotechnology-survey.htm
(please return to nikolaus.thumm@ipi.ch)

In general, we would appreciate if you could give as many additional comments to the questions as possible. If the provided space is not sufficient, please feel free to write on additional paper. All responses will be treated as highly confidential. The consolidated results of the survey will be made available to you.

If you have any questions or concerns please contact:

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Division of Legal and International Affairs
Swiss Federal Institute of Intellectual Property
Einsteinstr. 2
CH-3003 Bern
Tel. +41 (0)31 3232035, Fax +41 (0)31 3500608
nikolaus.thumm@ipi.ch

Please return the questionnaire to this address before

15th March, 2003
by using the attached envelope

Thank you very much for your co-operation.

Part A: General Questions

1. How important are patents for your company/institute in the context of:

	not important	modestly	medium	important	very important
The acquisition of venture capital?	☐	☐	☐	☐	☐
Mergers with other companies?	☐	☐	☐	☐	☐
Co-operations with other companies?	☐	☐	☐	☐	☐
Public funding of R&D?	☐	☐	☐	☐	☐
Timing of scientific publications?	☐	☐	☐	☐	☐
The number of scientific publications?	☐	☐	☐	☐	☐
The use of research tools?	☐	☐	☐	☐	☐
Others: ____	☐	☐	☐	☐	☐

2. Legal issues related to your company/institute

	never	rarely	sometimes	often	very often
Have you been sued due to patent infringements?	☐	☐	☐	☐	☐
Were you successful in these lawsuits?	☐	☐	☐	☐	☐
Have you sued other companies due to patent infringements?	☐	☐	☐	☐	☐
Were you successful in these lawsuits?	☐	☐	☐	☐	☐
Were the related costs for your company/institute high?	☐	☐	☐	☐	☐
Does your company need external legal advice on patents?	☐	☐	☐	☐	☐
Does your company possess in-house expertise in patent law?	☐	☐	☐	☐	☐

3. What percentage (%) of patentable inventions did you choose not to patent during the period 2000-2002?

0%	10%	20%	30%	40%	50%	60%	70%	80%	90%	100%
☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐

What are the reasons for your answer? Please explain briefly:

_____

_____

_____

Part B: Intellectual Property Rights Management

1. How important was each of the following methods for your company/institute in protecting inventions or innovations during the period 2000-2002?

	not important	modestly	medium	important	very important
Patents	☐	☐	☐	☐	☐
Trademarks	☐	☐	☐	☐	☐
Secrecy	☐	☐	☐	☐	☐
Long-term labour contracts	☐	☐	☐	☐	☐
Lead-time advantages	☐	☐	☐	☐	☐
Customer relations management	☐	☐	☐	☐	☐
Exclusive contract with suppliers	☐	☐	☐	☐	☐
Complex product design	☐	☐	☐	☐	☐
Embodying intangibles in products (i. e. software in machinery)	☐	☐	☐	☐	☐
Others: ____	☐	☐	☐	☐	☐

2. How many patent applications have been filed by your company/institute in the field of biotechnology during 2000-2002?

Number: ☐☐☐☐ biotechnology patent applications filed

How many biotechnology patents were you granted during 2000-2002?

Number: ☐☐☐☐ biotechnology patents granted

How many DNA patents did you apply for during 2000-2002?

Number: ☐☐☐☐ DNA patent applications

How many DNA patents were you granted during 2000-2002?

Number: ☐☐☐☐ DNA patents granted

3. Which countries are the 10 most important for your company/institute to apply for patent protection (Please list them in order, starting with the most important)?

1. _____ 6. _____
2. _____ 7. _____
3. _____ 8. _____
4. _____ 9. _____
5. _____ 10. _____

4. How important are the following motives for your company/institute in applying for a patent?

	not important	modestly	medium	important	very important
Protect own technology from imitation	☐	☐	☐	☐	☐
Prevent competitors' patenting and application activities	☐	☐	☐	☐	☐
Generate licensing income	☐	☐	☐	☐	☐
Improve the situation in R&D co-operations	☐	☐	☐	☐	☐
Improve inter-firm negotiations (cross licensing, joint ventures)	☐	☐	☐	☐	☐
Prevent patent infringement suits	☐	☐	☐	☐	☐
Improve the technological image of your company	☐	☐	☐	☐	☐
Acquire venture capital	☐	☐	☐	☐	☐
Others: ____	☐	☐	☐	☐	☐

5. To which degree do you practice the following patenting strategies?

	never	rarely	sometimes	often	very often
Examine competitors` patent portfolio	☐	☐	☐	☐	☐
Evaluate the state-of-the-art in a technological field	☐	☐	☐	☐	☐
Exert a purely defensive patenting strategy (protection of own technology)	☐	☐	☐	☐	☐
Exert an offensive patenting strategy (blocking of foreign technology)	☐	☐	☐	☐	☐
License in foreign technology	☐	☐	☐	☐	☐
License out own technology	☐	☐	☐	☐	☐

6. Have you had experience with

patent pools	☐	☐	☐	☐	☐
cross licensing	☐	☐	☐	☐	☐
patent consortia	☐	☐	☐	☐	☐

Which patenting and licensing strategies and tactics have been commercially successful in your company? Please explain briefly:

Part C: DNA patents

1. Based on the experiences of your company/ institute, to what extent do you agree with the following?

	no agreement				total agreement
The EU directive on legal protection of biotechnological inventions (98/44/EEC) provides an adequate legal framework for DNA patents.	☐	☐	☐	☐	☐
The ethical level set by this directive is sufficiently high for DNA patents.	☐	☐	☐	☐	☐

Please explain:

_____

_____

2. How often has your company experienced the following problems with DNA patents?

	never				very often
Unawareness of research staff about patenting	☐	☐	☐	☐	☐
Difficulties to enter a technological field because of too many patents	☐	☐	☐	☐	☐
Submarine patents in the field	☐	☐	☐	☐	☐
Patents, blocking access to technologies	☐	☐	☐	☐	☐
Patents, impeding further R &D	☐	☐	☐	☐	☐
Conflicting and overlapping patents	☐	☐	☐	☐	☐
Dependency on previous patents (crowded art)	☐	☐	☐	☐	☐
Patents hampering research co-operations	☐	☐	☐	☐	☐
Proliferation of legal patenting disputes	☐	☐	☐	☐	☐
Over-complex patent licensing negotiations	☐	☐	☐	☐	☐
Break down of patent rights negotiations	☐	☐	☐	☐	☐
Individual royalties are too high	☐	☐	☐	☐	☐
Accumulation of too many royalties for too many different patent holders	☐	☐	☐	☐	☐
Ethical problems	☐	☐	☐	☐	☐
Others: ____	☐	☐	☐	☐	☐

Please elaborate:

_____

_____

3. **According to the experience of your company/institute, do you think that the following remedies (listed vertically) address the problems listed horizontally? Please put a cross in the box provided if you agree that the remedy works effectively.**

	Increase(s) the access to genetic inventions	Integrate(s) complementary technologies	Reduce(s) transaction costs	Clear(s) blocking positions and avoid (s) litigation	Promote(s) the dissemination of technology
Patent pools	☐	☐	☐	☐	☐
Consortia	☐	☐	☐	☐	☐
Cross licensing	☐	☐	☐	☐	☐
Introduction of a grace period	☐	☐	☐	☐	☐
Introduction of provisional applications	☐	☐	☐	☐	☐
Maximum royalty fees	☐	☐	☐	☐	☐
Broad research exemption	☐	☐	☐	☐	☐
Protection limited to concrete disclosure functions of DNA	☐	☐	☐	☐	☐
Others	☐	☐	☐	☐	☐

Comments:

Part D: Genetic Testing

1. **According to the experience of your company/institute, to what extent do you agree with the following statements on patents in the field of genetic testing?**

	no agreement				total agreement
Patent owners or licensees prevent laboratories from continuing testing services.	☐	☐	☐	☐	☐
Tests were not developed due to the existence of patents.	☐	☐	☐	☐	☐
Our research staff is unaware of the legal implications of using patented research tools.	☐	☐	☐	☐	☐
Patents have a negative impact on access to genetic testing.	☐	☐	☐	☐	☐
Patents increase costs of genetic testing.	☐	☐	☐	☐	☐
Patents increase the quality of genetic testing.	☐	☐	☐	☐	☐
Patents improve the information sharing between researchers.	☐	☐	☐	☐	☐
Patents on genetic tests can lead to abusive monopoly positions.	☐	☐	☐	☐	☐

2. **How do you evaluate the efficacy of the following remedies in overcoming the issues mentioned regarding patents in the field of genetic testing?**

	very low				very high
Compulsory licenses	☐	☐	☐	☐	☐
Anti-trust laws	☐	☐	☐	☐	☐
Clinical use exceptions	☐	☐	☐	☐	☐
Change of patentability criteria	☐	☐	☐	☐	☐
Public pressure	☐	☐	☐	☐	☐
Offering clinical laboratories non-exclusive licenses to range a patented genetic test on reasonable terms	☐	☐	☐	☐	☐
Others ____	☐	☐	☐	☐	☐

Comments:

Please use this additional space for further comments or suggestions:

Part D: Firm data

Do you represent
-private company ☐
-public research institute ☐

What is your company's core business or primary sector of activity?

_____

_____

When was your company established? ☐☐☐☐

Number of employees ☐☐☐☐☐☐

Number of employees in R&D ☐☐☐☐☐

Total turnover 2000 (mill CHF) ☐☐☐☐☐☐

R&D expenditure in % of total turnover ☐☐☐

Export in % of total turnover ☐☐☐

(Instead of filling in the following points, you can staple your businesscard here.)

Country of residence: _____

Company name: _____

Street: _____

ZIP: _____

Person to contact: _____

Position in the company: _____

Tel./Fax: _____

E-mail: _____

15. Annex 26 (follow-up questionnaire)

Questionnaire on Research and Patenting in Biotechnology

Follow-up

We would like to ask you to kindly fill-in the enclosed questionnaire. It will take only about twenty minutes to complete it (You will also receive an electronic version which can be returned to nikolaus.thumm@ipi.ch).

We would appreciate as many additional comments to the questions as possible. If the space provided is not sufficient, please feel free to write on additional paper. All responses will be treated as highly confidential.

Please direct any questions or concerns to:

Dr. Nikolaus Thumm
Economic Counsellor
Division of Legal and International Affairs
Swiss Federal Institute of Intellectual Property
Einsteinstr. 2
CH-3003 Bern
Tel. +41 (0)31 3232035, Fax +41 (0)31 3500608
nikolaus.thumm@ipi.ch

Return the questionnaire to the above address before

10th September, 2003
using the enclosed envelope

Thank you very much for your co-operation.

1. **The first questionnaire showed that very few companies have been involved in patent litigations, either as plaintiff or defendant. In terms of your company/institute's experience, what would be the reasons for the low number of patent litigations in Switzerland?**

	no agreement				total agreement
Legal costs are too high in Switzerland	☐	☐	☐	☐	☐
Low confidence in the judiciary system in Switzerland	☐	☐	☐	☐	☐
The low quality of judges in Switzerland	☐	☐	☐	☐	☐
Alternative Dispute Resolutions is predominant	☐	☐	☐	☐	☐
Litigation rarely occurs in Switzerland	☐	☐	☐	☐	☐
Patent litigation is better handled outside of Switzerland	☐	☐	☐	☐	☐

If you believe that litigation is better handled outside of Switzerland, where do you prefer to litigate?

Germany	☐	USA	☐
France	☐	Japan	☐
Elsewhere	☐	United Kingdom	☐

Country? _____

2. **The first questionnaire revealed a high level of secrecy and patenting at the same time among the responding companies in Switzerland. We would therefore like to know:**

What percentage (%) of your patentable **product inventions** did you choose not to patent during the period 2000-2002.

0%	10%	20%	30%	40%	50%	60%	70%	80%	90%	100%
☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐

What percentage (%) of your patentable **process inventions** did you choose not to patent during the period 2000-2002.

0%	10%	20%	30%	40%	50%	60%	70%	80%	90%	100%
☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐

Which of the following motives are of relevance for you company/institute <u>not</u> to patent potentially patentable inventions?

	not relevant				very relevant
Patents are too expensive	☐	☐	☐	☐	☐
Patent protection requires disclosure of important information about inventions	☐	☐	☐	☐	☐
Publication in scientific journals are more important to us	☐	☐	☐	☐	☐
Low confidence in the enforcement possibilities of the judiciary system	☐	☐	☐	☐	☐
Difficulties with the legal enforcement of process patents	☐	☐	☐	☐	☐
Difficulties with the legal enforcement of product patents	☐	☐	☐	☐	☐
We only have small step inventions (improvements).	☐	☐	☐	☐	☐
Legal insecurity with biotechnology patents in the European Union	☐	☐	☐	☐	☐
Legal insecurity with biotechnology patents in Switzerland	☐	☐	☐	☐	☐
Other motives: _____	☐	☐	☐	☐	☐

3. **Another finding is that companies have low experience with patent pools, cross licensing and patent consortia. Which reasons would you give for this low experience which are relevant to your company/institute?**

	patent pools	cross licensing	patent consortia
We are not convinced of the effectiveness of	☐	☐	☐
We do not know how to use	☐	☐	☐
We experienced major difficulties using	☐	☐	☐
We miss legal regulations	☐	☐	☐
We are cautious about collaborating with competitors and therefore reluctant to use	☐	☐	☐
We have anti-trust concerns about using	☐	☐	☐

4. **The EU directive on the legal protection of biotechnological inventions was welcomed moderately by all respondants, yet there seems to remain a certain degree of reluctance against it. Do you share any of the following concerns about the implementation of the EU directive in Switzerland**?

	no agreement				total agreement
The directive is unclear	☐	☐	☐	☐	☐
The directive is too restrictive	☐	☐	☐	☐	☐
The directive is too liberal	☐	☐	☐	☐	☐
The directive is not appropriate for Switzerland	☐	☐	☐	☐	☐
The directive hampers research	☐	☐	☐	☐	☐
The directive is ethically insufficient	☐	☐	☐	☐	☐

In particular, do any of the following regulations of the directive concern you:

	no concerns				many concerns
The regulation on morality (Article 6)	☐	☐	☐	☐	☐
Concretely disclosed functions of DNA patents are not regulated	☐	☐	☐	☐	☐
A research exemption is missing	☐	☐	☐	☐	☐
The farmers exemption is too restrictive	☐	☐	☐	☐	☐
A regulation on Prior Informed Consent (PIC) is missing	☐	☐	☐	☐	☐
A regulation on access-benefit sharing is missing	☐	☐	☐	☐	☐
Other concerns Please specify: _____	☐	☐	☐	☐	☐

5. The introduction of a grace period was not welcomed. From your company/institute's point of view, what are the reasons <u>against</u> a grace period?

	no agreement				total agreement
The concept of a grace period is poorly defined	☐	☐	☐	☐	☐
A grace period creates legal uncertainty for third parties	☐	☐	☐	☐	☐
It creates a misleading perception of security	☐	☐	☐	☐	☐
It is not necessary when people are adequately informed of how the patent system functions	☐	☐	☐	☐	☐
Only an introduction at international level is useful	☐	☐	☐	☐	☐
Other concerns Please specify: _____	☐	☐	☐	☐	☐

6. The introduction of a research exemption was believed to be relatively beneficial. How would you like to see a research exemption actually implemented in Switzerland?

	not at all				very much
Same as in the USA	☐	☐	☐	☐	☐
Same as in Germany	☐	☐	☐	☐	☐
Broader than in Germany	☐	☐	☐	☐	☐
More restrictive than in Germany	☐	☐	☐	☐	☐
It should include a clinical use exemption	☐	☐	☐	☐	☐
It should include an exemption for genetic testing methods	☐	☐	☐	☐	☐
Should comprise an exemption for diagnostic tests.	☐	☐	☐	☐	☐
It should not be undermined by Material Transfer Agreements (MTA)	☐	☐	☐	☐	☐
Other forms Please specify: _____	☐	☐	☐	☐	☐

7. The limited protection of DNA patents to concrete disclosed function of DNA was widely welcomed in the first questionnaire. How do you assess the actual implementation of such a regulation for Switzerland?

	no agreement				total agreement
A concrete disclosure of the function enables the restriction of patent claims	☐	☐	☐	☐	☐
A limitation of the scope of protection should be provided for in patent legislation	☐	☐	☐	☐	☐
The absolute protection of DNA patents is hampering research and further development.	☐	☐	☐	☐	☐
Limited protection of DNA patents is for our purpose more important than absolute protection	☐	☐	☐	☐	☐

8. Licensing of patents is obviously essential for the business of many biotechnology companies and research institutes. How would you evaluate the following measures/statements with respect to licensing?

	no agreement				total agreement
We had difficulties finding licensing partners	☐	☐	☐	☐	☐
Non-exclusive licensing as an effective measure	☐	☐	☐	☐	☐
The threshold for compulsory licensing is too high (not effective)	☐	☐	☐	☐	☐
A compulsory licensing regulation would be important in cases where abusive monopoly positions are apparent	☐	☐	☐	☐	☐
Independent research and freedom to operate are endangered by cases like the Myriad one?	☐	☐	☐	☐	☐
The accumulation of too many royalty fees impedes effective licensing	☐	☐	☐	☐	☐

9. Firm data

Are you affiliated with a:
-private company ☐
-public research institute ☐

Number of employees ☐☐☐☐☐☐

Number of employees in R&D ☐☐☐☐☐