SETTERWALLS

Life Sciences

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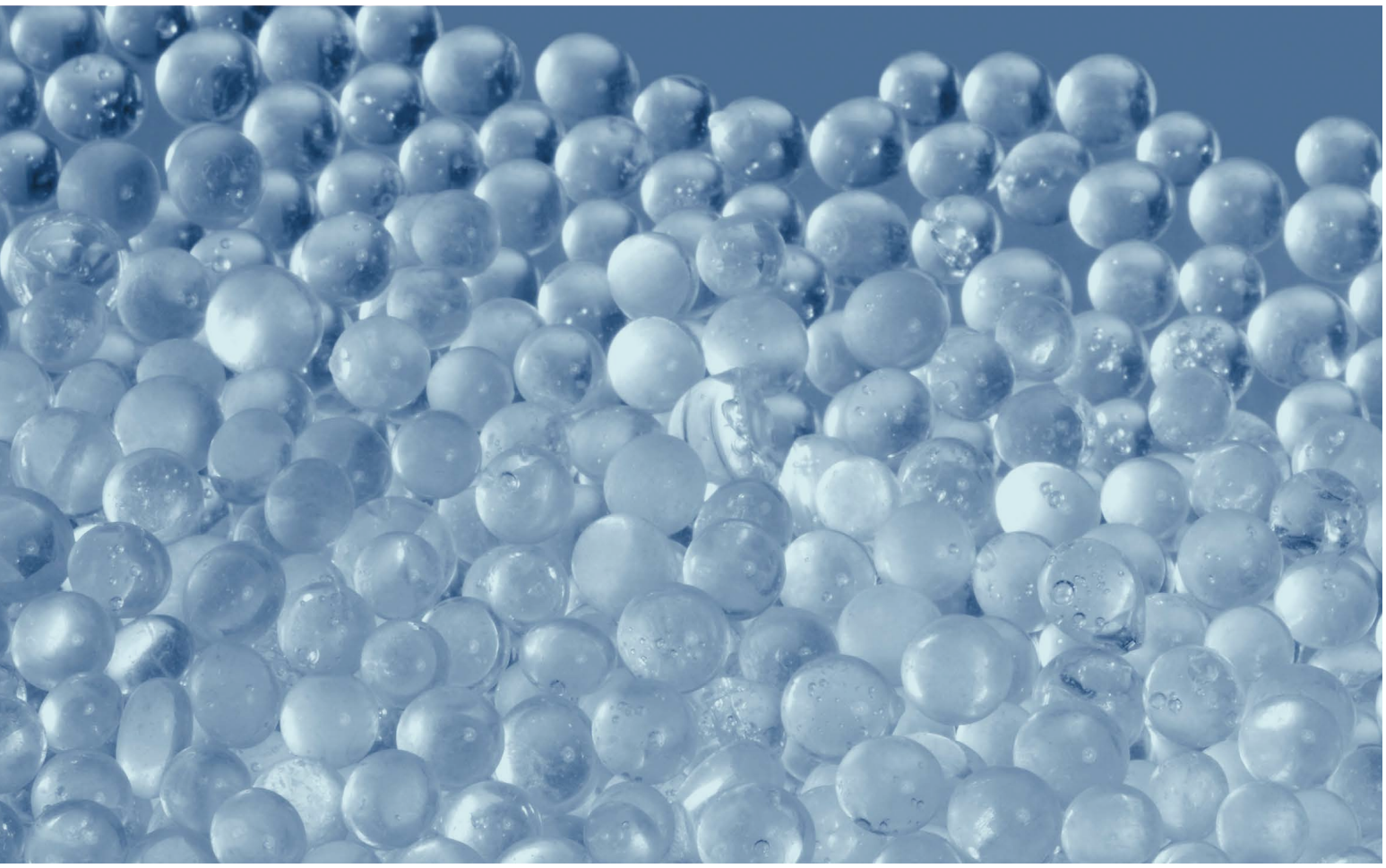

In this issue of Life Sciences Report you can read about a recent report from the Dental and Pharmaceutical Benefits Agency regarding prescription drugs outside the pharmaceutical benefit scheme. You can also get some updates on the EU Patent Package; The 18th draft of the rules of procedure was recently presented and the preparatory committee is expected to agree on a final set of rules at its meeting this month. We also summarise some of the more interesting novelties which are proposed to be introduced in the Swedish legislation on public procurement in connection with the transposition of the EU directives. These are just some of the interesting articles in the field of life sciences. Our guest contributor, Mr. Kenneth Nyblom, managing director for the Generic Pharmaceutical Association in Sweden, writes about his observations on in the field of pharmaceuticals. And don't forget, you are always welcome to contact us at Setterwalls to take a more in-depth look at these and other issues.

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Guest contributor Mr. Kenneth Nyblom

Increased proportion of generics, biosimilars and innovative new medicines – at the same cost?

Denmark is usually cited as a pioneer in the use of innovative new medicines. While Denmark uses a greater proportion of newly introduced drugs, they also use more generics and biosimilars than we do in Sweden. How is this possible? The explanation is quite simple. These drugs are not opposed to one another; on the contrary, they are related. In order to be able to afford expensive new drugs, cost-effective medicines must be used whenever possible. The idea that Sweden does not invest in innovations and instead just focuses on generics is incorrect. On the contrary, Sweden actually has a lower percentage of generic drugs than, for example, the US, UK, Denmark and Germany – countries usually regarded as frontrunners regarding the introduction of innovative medicines. A few months after patent protection of Remicade expired, the two Infliximab biosimilars had captured a 94% market share in Denmark, 75% in Norway, 40% in Finland, but only an 8% market share in Sweden. With that attitude, it is perhaps not surprising that no money is left over to invest in new medicines. The attitude towards switching existing patients is also an interesting issue in this context. The originator industry often asserts that existing patients should not change and thus implicitly, only new patients should be started on biosimilars. Based on that premise, patent expirations on biologics are barely noticeable in healthcare budgets, thereby also limiting the potential to launch new medicines. The Association for Generic Pharmaceuticals in Sweden (Föreningen för Generiska Läkemedel, FGL) believes that switching patients during treatment is possible, as long as it takes place under medical supervision with structured follow-up. This means that the treating physician should be involved in the change and thus biologics should not be substituted at the pharmacy.

Unlike biological drugs, most generic drugs are suitable for substitution at the pharmacy. Sweden has a very efficient generic substitution system. The Swedish Dental and Pharmaceutical Benefits Agency (Tandvårds och Läkemedelsförmånsverket, TLV) estimates that the system produces an annual savings of SEK 8 billion. This money can be used for more expensive treatment for those patients who really need it.

The basic principle of the Swedish generic model is to allow generic suppliers to compete with open and transparent prices. The system assumes that pharmacies cannot choose their supplier, but are instead obligated to provide the least expensive drug.

When the pharmacy market was privatised, many people doubted that the current competition with open and transparent prices would work with private pharmacies. It was feared that generic suppliers would be too dependent on pharmacy chains to dare to lower prices (which would negatively impact pharmacies' future profits). When Norway reregulated its pharmacy market, the government had initially hoped for price competition – but that never materialized. The Swedish system is unique in that each reduction of the pharmacies' wholesale price (apotekens inköpspris, AIP) corresponds with the same reduction of the retail price (apotekens utförsäljningspris, AUP). Only one country has succeeded with the same feat as Sweden – Denmark. Denmark and Sweden also have the lowest retail price for generics. The same generic companies are in Sweden, Denmark and Norway, and the same tablets in containers come from the same factories. When the generic companies drop their price in these three countries at the same time on the same products, the retail price automatically drops in Sweden and Denmark, which provides savings for taxpayers and patients. In Norway, the entire price difference lines the pockets of the pharmacy chains. It is easy to understand why the Swedish Pharmacy Association is eager to adopt the Norwegian model.

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Is it appropriate to conduct a review of the benefit scheme without reviewing the price regulation at the same time?

The Dental and Pharmaceutical Benefits Agency (Sw. Tandvårds- och läkemedelsförmånsverket, hereafter "TLV") recently issued a final report about prescription drugs outside the pharmaceutical benefit scheme. The report investigated the increase of the number of prescription drugs withdrawn from the benefit scheme and a trend in which pharmaceutical companies are choosing not to apply for entry.

Referral bodies have just submitted their comments. They express criticism that the TLV's remit was limited to reviewing the benefit scheme and did not include price regulation. Many indications suggest that the TLV's proposal to subject drugs outside the benefit scheme to substitution will not have the intended effect of pharmaceutical companies keeping their drugs in the benefit scheme. The proposals therefore risk having no merits in relation to the purpose of the remit.

The discussion about pharmaceutical companies withdrawing prescription drugs from the benefit scheme and choosing not to apply for entry has been pursued for some time. As a result, the government tasked the TLV with investigating the consequences of such actions, the reasons for these trends, and to propose measures for counteracting the negative consequences for patients and the healthcare system.

However, the TLV's remit did not include a review of price regulation. TLV's final report, which was published before the summer, presents proposals that include allowing substitution of drugs not covered by the benefits scheme at the pharmacy and implementing an independent website where prices for all prescription drugs can be compared.

The purpose of the Swedish benefit scheme is to safeguard high drug costs. There is an inherent desire to have as many prescription drugs covered by the benefit scheme as possible.

Today the scheme covers almost 14,000 different types of medications and other goods. The TLV decides what products may be included and at what price. Not all prescription drugs are covered.

Medicinal products which are not included are subject to free determination of price, which means that the price may vary from one pharmacy to another. Under the current system, pharmacies may not substitute less expensive drugs that are covered by the benefit scheme for drugs that are not covered by the scheme.

What then is the reason that a drug is not covered by the benefit scheme? One frequent argument is that pharmaceutical companies choose to withdraw drugs from the scheme to avoid competition from generics. Of course withdrawal may also be due to other factors, such as rejection by the TLV because the cost is too high, the drug can only treat less serious medical conditions, or the TLV may refuse a request for a price increase.

In the discussion, responsibility for withdrawal is often placed on the pharmaceutical companies. However, for the pharmaceutical companies, the issue is more complex, largely due to inadequate interaction between the benefit scheme and pricing policy.

Companies (regardless of industry) always seek to compensate their costs for their products. If the benefit scheme does not allow pharmaceutical companies to cover the cost

of their products, companies may request withdrawal from the scheme. One example of drugs for which the complex problem has now become more pronounced involves drugs covered by the scheme that are more than 15 years old. Under a recently introduced requirement, the prices of these drugs must be reduced by 7.5 percent, which affects the possibility of keeping them within the benefit scheme.

Against this background, it is questionable whether it really is appropriate to conduct a review of the benfit scheme without also reviewing price regulation at the same time. Various industry representatives have repeatedly argued this point and several referral authorities have also criticized this point.

There are many indications that TLV's proposals, such as substitution, will not influence decisions by companies to withdraw unprofitable products from the benefit scheme. There is also a risk that the long-term effect of the proposals may be that drugs that are not covered by the benefit scheme will instead disappear from the market. The proposals therefore risk having no effect in relation to the purpose of the remit.

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EU Patent Package

For the EU to be more competitive in relation to the US and Japan, a single patent title has been discussed for a long time. The 18th draft of the rules of procedure was recently presented and the preparatory committee is expected to agree on a final set of rules at its meeting this month.

We previously reported on the new patent package that is to come into force within the EU. Since our last article in the Life Sciences Report there have been some updates that we would like to report.

The EU has been discussing a single patent title providing uniform protection throughout the EU for at least 30 years. By signing the Unified Patent Court ("UPC") Agreement

we may now have reached the goal. The UPC Agreement was approved December 2012 within the EU along with a regulation creating unitary patent protection (Regulation 1257/2012) and a regulation establishing language rules. These three instruments have been referred to as the EU patent package. Sweden ratified the UPC Agreement on June 5, 2014. Very recently Italy announced that it also wants to join the UPC Agreement, which means that 26 member states are now participating in the initiative.

As previously stated, unitary patents will be granted by the European Patent Office (EPO) but will constitute a single patent title providing uniform protection and equal effect. The patentability requirements and term of protection will be the same as for European patents today.

The UPC will also have jurisdiction over enforcement of existing European patents. The court system will include a Court of First Instance and a Court of Appeal. So-called Local and Regional Divisions form a part of the Court of First Instance. In addition there is a Central Division in Paris with departments in London (for i.a pharma-related issues) and Munich (for mechanical engineering). In March 2014 Sweden, Estonia, Latvia and Lithuania signed an agreement on the establishment of a Nordic-Baltic Regional Division of the UPC, which would be located in Stockholm. The language of the proceedings will be English. The Court of Appeal in the UPC system will be based in Luxembourg.

Decisions under the UPC system will be effective and binding in all participating states. This means that a revocation of a patent or a decision concerning infringement will have effect in all participating member states.

The UPC will handle cases concerning unitary patents as well as European patents, including previously granted patents following a transition period of seven years from the date of entry into force of the UPC agreement. During the transition period rightholders of traditional European patents may "opt out" of the UPC system. An opt out means that a European patent will remain subject to the national system we know today. However, a rightholder may choose at any time during the transition period to opt in to the UPC system.

Spain has lodged two appeals against the regulation, but on May 5, 2015, the Court of Justice dismissed Spain's actions, which means that the implementation process has continued.

Furthermore, on October 1, 2015, a protocol to the UPC Agreement was signed by representatives of member states, allowing some parts of the Agreement to be applied early. For example, the rules regarding recruitment of judges will come into force earlier and early registration of opt out demands will also be permitted.

However, there is still a ways to go before the system becomes operational. Before the unitary patent comes into effect it must be ratified by 13 member states, including France, Germany, and the United Kingdom. France is the only country of these required member states that have ratified the Agreement to date.

The estimated timeframe is that the preparatory committee will complete its work by June 2016 and the UPC will begin in early 2017. Life Sciences Report will follow the developments.

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Focus of the new phamaceutical and pharmacy investigation

Pharmacies have been the subject of continual investigation over the past ten years. Earlier this year the government announced that yet another investigation will be conducted, aimed at improving access to medicines, among other things. On November 19, 2015 the government presented a new investigation.

Ten years of investigation

About ten years ago, on May 31, 2005, the European Court of Justice gave judgment in the case Hanner (C-438/02). The Court found that the agreement that Apoteket AB then had with the Swedish state (1996 agreement), may put medicinal products from other Member States at a disadvantage compared with Swedish medicinal products. The state monopoly thus was not designed in such a way that all discrimination against medicinal preparations from other Member States was excluded. Thus the monopoly was contrary to Article 31(1) EC.

In response to this judgment, on February 16, 2006, the Government at the time decided to conduct a review of the Swedish pharmacy monopoly. The investigator was to submit proposals for necessary changes to comply with Community law requirements on state monopolies. The investigator was specifically instructed to analyze whether the sales network of what was then Apoteket AB was designed to ensure consumer access to human and veterinary medicines.

While the issue of whether to preserve the monopoly is obviously a moot point, the second question, ensuring consumer access to medicines, remains relevant. This was

confirmed when the responsible cabinet minister earlier this year announced that the government intends to initiate a new pharmacy investigation.

The past ten years have been eventful in the pharmaceutical and pharmacy market. After a change of government in autumn 2006, a new pharmacy investigation was ordered (December 21, 2006) that was not aimed at adapting the monopoly to EU law, but was tasked with making it possible for other participants to engage in retail trade with

medicinal products: to "re-regulate" the pharmacy market. Re-regulation was implemented in 2009 and the pharmacy business was transferred in part to a number of private operators. The remaining issues related to re-regulation were investigated from June 2011 in the Pharmaceutical and Pharmacy Inquiry, which released a final report about one year ago, in December 2014. The official period for submitting comments on the final report expired as recently as last summer.

New inquiry

The Government has now adopted terms of reference for the new inquiry, called "Increased focus on quality and safety in the pharmacy market" (dir. 2015:118).

Åsa Kullgren (S), chair of the County Council in Sörmland, will head up the inquiry. The remit of the inquiry includes:

- Analysing developments in the pharmacy market since reregulation and assessing the short-term and long-term effects of the trends.
- Reviewing the requirements for obtaining a permit to run a retail pharmacy.
- Analysing measures that could be necessary to ensure good access to pharmacy services throughout Sweden.
- Analysing whether measures are necessary to ensure compliance with the obligation to supply and dispense medicinal products.
- Analysing whether there is a need for further measures to promote a high degree of direct dispensing or to improve the service provided when direct dispensing is not possible.
- Reviewing how the role of pharmacies in improving medication use can be expanded.

The terms of reference specifically stipulate that the inquiry chair should bear in mind that proposals should leave the current generic substitution model unchanged.

The report must be submitted by 31 December 2016.

Are these the most urgent questions?

Last summer the Swedish Pharmacy Association said that access to medicines has already improved and that one study shows that 95 percent of prescriptions are immediately dispensed. The Pharmacy Association points instead to conditions for developing drug counseling and services related to prescription drugs as important matters. Another issue that should be reviewed according to the Pharmacy Association involves the rules regarding distribution and returns, in order to further improve access to medicinal products.

In a document dated September 16, 2015, LIF states that there is no reason to investigate minor adjustments to the existing distribution model. Instead, the focus should be on taking advantage of the opportunities provided by increased digitization, for example through home deliveries directly to the patient. Furthermore, LIF underscored the need to reduce the improper use of medicines, where pharmaceutical counseling is an important aspect, and the need for a thorough investigation of the reimbursement system.

The pharmaceutical and pharmacy market has thus been the subject of continual investigations for the past ten years. It is therefore particularly important that yet another investigation has the right focus. Availability of medicines is crucial for all stakeholders, but there are also other matters of concern. One is improper medication use, which causes suffering and incurs costs. Pharmacies are an important resource for dealing with this problem and a separate reimbursement schedule was previously proposed. Another issue involves the processes for bringing new drugs to market under the reimbursement system. The pharmaceutical benefit scheme itself is therefore a question of accessibility. Perhaps this is a task for the next investigation in the area. We are following this issue with great interest.

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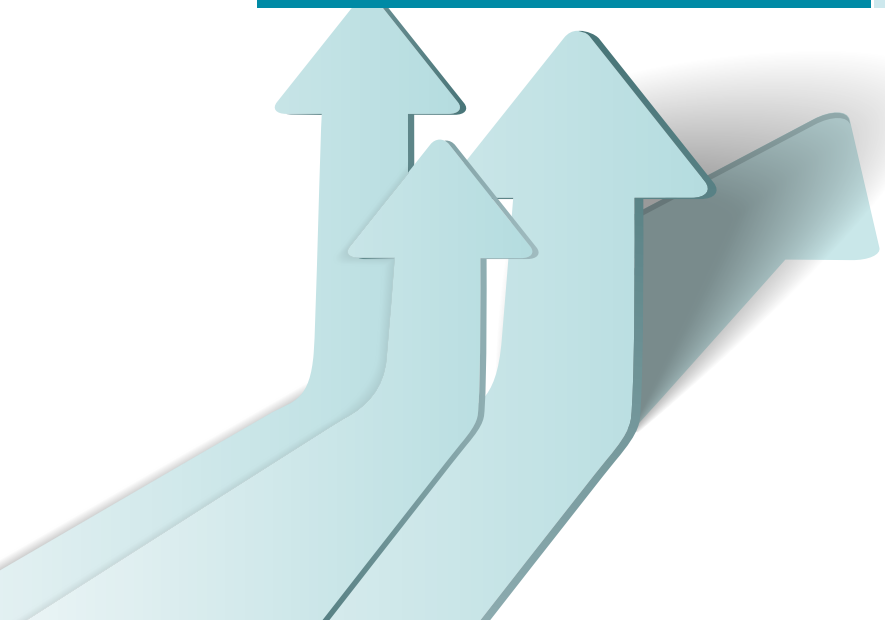
Do's and don'ts in the exit process within Life Sciences industry

There are several challenges in an exit process and particularly within the Life Sciences industry. Lack of funding might rush the process, while the emotional attachment of funders to the business might slow the process. Having an exit strategy is important from day one, but when you find yourself surrounded by bidders, advisors and others, there are still some legal do's and don'ts to consider. Here is a shortlist!

Do…	*Don't…*
… sign an engagement agreement with the advisors Before you initiate the exit process, sign an engagement agreement with both financial and legal advisers and make sure to choose and evaluate them beforehand. Find out their track record, are they part of an international network, how do they propose to conduct the process, what is included in their services (and what is not), what is the remuneration (fixed price or variable), and what are the terms of payment?	*… let regulatory approvals delay you* In the Life Sciences industry many acquisitions and disposals involve compounds or devices that have not yet received regulatory approval. However, don't let regulatory approval delay your exit. For example, additional payment, or contingent consideration arrangements based on the outcome of future events can be convenient ways of validating a company's value and of sharing economic risk between buyer and seller.
… sign a confidentiality agreement with the buyer In the confidentiality agreement both sides agree to keep discussions and materials related to the deal confidential. Remember to regulate how the information should be treated, who is allowed to receive the information and how long the confidentiality obligations are valid. Most important is perhaps that the confidentiality agreement prevents so-called "fishing expeditions" by unserious buyers who are simply looking to gain insight into your business.	*… wait with conducting vendor due diligence, which includes an inventory of all your agreements with customers, suppliers, consultants, CROs and universities etc.* In the due diligence phase, the buyer examines your books and records to confirm everything you have claimed. Vendor due diligence will let you know about your strengths and weaknesses before the buyer does and before you end up in discussions of appropriate considerations, liabilities and warranties. Also consider whether it is worth sharing information step by step, rather than revealing everything from the start.
… sign a letter of intent with the buyer A letter of intent addresses issues of confidentiality, the conditions for the acquisition, timetable and exclusivity. Remember: only the clauses concerning exclusivity, choice of law and confidentiality are binding; the rest of the agreement is considered to be a non-binding agreement.	*… forget to consider the transfer structure before the negotiations* Should the transfer be done as a share sale or asset sale? Cash considerations or other? All or some shares or newly issued shares? There are several different methods, all of which have different tax effects. Remember to that a share sale limits liabilities such as tax liabilities, outstanding guarantees, and pension obligations which will be transferred to the new owner, while an asset sale may be more complicated since the status of all assets must be reviewed (e.g. are they leased or pledged and is a transfer of them allowed).

Do…	Don't…
… remember that transfer of marketing authorization might take some time If the marketing authorization is to be transferred from the currently approved holder to a new holder (a different person/legal entity), this will most likely be done after signing, but before the deal closes. Remember that it might take some time. So don't forget to estimate and consider the time and potential delay in the timetable.	*… forget to consider if re-registration of intellectual property rights are required* In most cases, re-registration of intellectual property rights is not mandatory since it has no legal effect on ownership, but only on the rights *in rem*. Under Swedish law, both the patent application and the granted patent can be assigned by contract or inheritance.
… be aware of the fact that know-how is formally not recognized as an intellectual property right in Sweden Know-how is formally not recognized as an intellectual property right in Sweden, but is protected under the Trade Secrets Act (Sw. Lag om skydd för företagshemligheter, SFS 1990:409) if the know-how can be defined as a trade secret. Thus, if know-how should be part of the transfer it is not enough to specify it as intellectual property.	*… undertake far-reaching prohibition of competition* An entrepreneur who sells his/her company will often be forced to sign a prohibition of competition clause. Remember that such undertakings must be reasonable and may not last indefinitely. Customary is 2-3 years after the transaction depending on the scope.
… consider options other than a transfer of ownership such as joint ventures, consortium agreements, commercial research and development agreements, product distribution agreements or co-promotion agreements The above agreements may fulfill the same purpose as an exit. Partnering may grant funding, new ideas, maximize product presence on the market, and ensure solid continuation of practice with or without your help.	*… forget measures that might remain after closing* Even if the transaction has closed and you've successfully exited your company, don´t forget that there might be measures that remain or arise after closing, such as coverage of variable purchase price, integration and warranty claims. In order to monitor the buyer's activities you might want to include post-exit audit rights of the company in the acquisition agreement.



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Trademarks Basics

Sometimes we think we know it all. Many times this is not true. At least occasionally we need to get back to the basics and reboot. I thought I would share one such occasion with you and answer some common questions.

1 A trademark – what is it?

A trademark shall consist of a graphically representable sign that can serve to distinguish the origin of a product or service. The latter is the essential function of a trademark – to exclusively identify the commercial source or origin of products or services. Sometimes you can get trademark protection just by using a mark, so called acquired rights, but registration adds clarity and security for investments. Trademark registries are maintained by many national or regional trademark offices, such as the Swedish PRV, the EU OHIM and the US USPTO. The trademark owner can be an individual, a business organization, or any other legal entity.

Different goods and services have been classified by the International (Nice) Classification of Goods and Services into 45 so-called Trademark Classes (1 to 34 cover goods, and 35 to 45 services). The idea behind this system is to specify and limit the extension of the intellectual property right by determining what goods or services are covered by the mark, and to unify classification systems around the world.

A trademark thus has to be registered for the specific goods and/or services, for which it is or will eventually be used. A defensive barrier or similar goods and services are also often included to prevent other registrations from coming too close. Trademark protection for products and/or services for which the trademark is not used ultimately becomes subject to revocation, but that is another story. Moreover, a trademark must be able to distinguish your products within a particular category from those of others. This means that the mark cannot just describe the product or type of product (like CAMERA for a camera) or a generic claimed quality of any product (like HIGH QUALITY).
As initially pointed out, a trademark must be graphically representable. Typically this is manifested by product/service names (brands) and taglines (the main category would be word marks, such as Coca-Cola® or Just Do It® - the former property of The Coca-Cola Company and the latter owned by Nike®). The other main category would be logos and other graphic elements (this category is often referred to as figurative marks, such as the Nike "Swoosh" symbol), but that is not all. For example, musical tunes have been registered by registering the sheet music, and even smells have been registered in the form of a verbal description of the smell.

2 What's the difference between a trademark, a copyright and a patent?

A trademark is legal protection for your brand, intended to ensure that competitors do not market similar products under a similar name, with a similar logo, in the same kind of packaging, etc. Copyright protects a literary or artistic work manifested concretely, examples comprising a book, a drawing or painting, a computer program, photographs etc. Protection is afforded against actions such as unauthorized copying, public displays or exhibitions.
A patent protects a new and inventive industrially usable technical achievement (an invention) against unauthorized commercial use by others.

A patent requires registration and can be expensive since there is a rather complicated prosecution process leading up to a grant, whereas copyright protection is automatic as long as the work is original enough to be awarded protection.
It could be said that trademarks are somewhere between patents and copyrights. As stated above, trademark protection can be obtained through use without registration, but a registered trademark is safer than relying on such acquired rights and typically not nearly as costly as a patent. Both

trademarks and patents (as well as designs and some other intellectual property rights collectively known as industrial property rights) are territorially restricted rights (only valid in specific jurisdictions), whereas a copyright is automatically recognized worldwide (almost).

As far as the duration of protection is concerned, a patent is granted for up to 15 years (20-something years in the pharmaceutical business, where various extensions are possible). A patent must be renewed annually against a fee. The renewal fees increase substantially toward the end of the validity term. A copyright is typically valid throughout the "author's" lifetime plus an additional 50 - 70 years (national differences exist). A trademark registration must typically be renewed every 10 years, but as long as the trademark is still used in commerce, the registration can be renewed in perpetuity.

3 Isn't it enough that my company name is protected?

Yes and no. A registered trade name (Sw. firma) receives some of the protections granted a registered trademark, but the protection is weaker and narrower. A registered trade name basically only protects you against bad-faith use of your "mark" by others. In most jurisdictions, if someone else files an application to register your trade name as a trademark before you do, you must respond and file your opposition against the application within a specific timeframe. In Sweden, if there is a confusing similarity between the trade name and the applied trademark, registration of the trademark will not be allowed, but in many jurisdictions such opposition will usually only succeed wholly if you can document that the applicant knew about your trade name before they started using it – so-called bad faith. The scope of protection granted a Swedish trade name is further limited by the registered business activity (Sw. verksamhetsbeskrivning).

4 Trademark cover – for what should I seek protection?

Your trademark should cover classes that include the core activities of your business. At the risk of sounding somewhat unprofessional – one easy solution is to review your competitors' trademark registrations to see what products they have included and see if that makes sense. Regardless, prepare to describe your business, present and future, for your trademark counsel and ask him/her. It is important to note that different trademark registries have different policies regarding the list of goods and services. In the US, you have to document actual commercial use of the mark for the products in question, whereas in Europe in general and Sweden in particular, you do not (but as stated above - non-use can lead to revocation).

5 Where should I register my trademark?

Unlike copyright, which is (almost) automatically awarded protection worldwide, trademarks are territorially limited exclusive rights. This means that you must register your trademark at the trademark offices/registries in all jurisdictions where you plan to use your trademark and want to protect it through registration. For example, registration in Sweden, will provide some provisional protection or priority for your application in other jurisdictions, which must be filed within a certain time. You do need to act promptly if you discover that your first application has inspired someone else to use or register your mark. Filing in the main market first provides a good indication and initial reaction from the trademark office in question, which may be helpful when considering a decision on investing further in the applied-for trademark. If you want to file an application in several countries right from the start, international registration through WIPO is a convenient option, but eventually you will have to deal with the individual trademark offices, each of which processes the application and any related obstacles separately.

6 Can I do it myself or do I need a trademark counsel?

It is indeed possible to file a trademark application without counsel. The application per se is not rocket science. The considerations on how to complete the application and effectively formulate its details and scope, however, is a different matter. It is generally advisable to retain some kind of professional assistance to help you with clearing the mark, drafting and filing the application (especially the list of goods and services), communication with the trademark office after filing in case your application must be amended to proceed to a grant, and definitely advisable if you face opposition or other proceedings that may arise.

7 What about costs?

Costs for a trademark application can roughly be divided into three categories: 1. Official application fees charged by the relevant trademark office typically range from SEK 2,000 to 3,000 per jurisdiction. For an EU-wide CTM application, the official fee is in the range of SEK 9,500. Additional classes of products added to your application will increase the official fees. Before you get this

far, however, you would usually, or in my opinion should, engage trademark counsel to help you clear the mark and prepare the trademark application, which, including search costs, will add at least a couple of thousand SEK. Although no guarantee for smooth sailing, this is well-invested money; navigating an application through opposition and/or other litigation will multiply the costs several fold.

8 I have already registered my trademark, now what?

Good for you! However, don't get too comfortable yet. You should be aware of the following:

Use your mark. If you don't, it can be revoked.

Remember to renew your mark. If you have retained trademark counsel, they will help you to do this. A trademark registration will typically expire after a period of ten years, but can be renewed as many times as you want, provided you (often through your trademark counsel, pay the renewal fees.

Monitor your trademark for infringement and third party use of similar marks. In most jurisdictions, if someone applies for registration of an identical or similar mark for similar products, you must file an opposition within a certain timeframe after the new application has been published. Again, if you have retained a trademark attorney, they will or at least can help you to do this. Monitoring services come at a cost of SEK 3,000 – SEK 10,000 annually per mark, depending on the geographical scope and number of classes monitored. If someone is using a mark similar to yours in a commercial context, you should promptly react with a cease-and-desist letter. In such cases you have definitely crossed a line – retain a trademark counsel to help you. Failure to file opposition or demand cease-and-desist can constitute acceptance and make it virtually impossible, or at least substantially more costly, to successfully take any legal measures later on. If you are considering a "live and let live" attitude toward a similar trademark application or use, please note that this will weaken your brand and may cause confusion in the marketplace.

9 The trademark symbols - ®, ™, ª/c

® is the symbol for registered trademarks; use this only if and when you have obtained registration for your trademark. In some jurisdictions, such as the UK, use of the ® symbol without an actual registration is specifically illegal, while in other jurisdictions doing so may be considered to be misleading advertising. The ® symbol is often also used to acknowledge the existence of third-party trademark rights, whether in marketing materials or reference works, such as this article. ™ is a symbol used for (unregistered) trademarks where you want to mark your turf – it simply sends the signal that you consider this to be a trademark and that "This trademark is mine and I will defend it." The seldom-used ª/c symbol (really only in the US) is for service marks (unregistered) and otherwise the same as ™.

10 I have seen that trademarks are often written in CAPITALIZED letters, why?

Tradition, mostly. It has no legal significance. Using capitalized letters or inserting a space in parts of the mark can, however, change how the mark is perceived. For example, MORETIME is not quite the same as more time, Moretime, or MoreTIME. Again, this has no immediate legal significance and is quite rare.

11 What is the correct term – trademark, trade mark or trade-mark?

There is no right or wrong here. The use depends on the jurisdiction. "Trademark" as one word is commonly used in the US, among others. "Trade mark" in two words is (declining however in my mind) more common in the EU, among others. Do not use the hyphenated version, unless you are in Canada.

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BRANDING
MARKETING
TRADEMARK
SYMBOL
ADVERTISING
MISSION
BUSINESS
CORPORATE
MANAGEMENT
IDENTITY
NAME
CLASS
NET
FIRM
LOGO
FORM
TECHNOLOGY
STRATEGY
INTERBRAND
DESIGN
MARK
MARKER
CREATIVE
DIRECT
PRODUCT
CLIENT
NAMING
SOURCE
BRANDING
EXPERT
IMAGE
STAMP
LOYALTY
ADVERTISING

New procurement rules – Noted novelties

The European Parliament and the Council adopted three new directives relating to public procurement on 26 February 2014, and the transposition period for the member states will expire on 18 April 2016. In the following, we summarise some of the more interesting novelties which are proposed to be introduced in the Swedish legislation on public procurement in connection with the transposition of the EU directives.

The transposition of the directives into the Swedish legislative framework will include new legislation on public procurement in the "classic sector" and in the utilities sector (water, energy, transport and postal services), as well as on the award of concession contracts. The new legislative proposals are quite extensive, and the proposal submitted to the Swedish Legislative Council has 1495 pages. From a general perspective, the proposal largely consists of modifications of a more administrative nature, such as mandatory use of electronic communication, reduced minimum period to submit a tender, and the possibility for tenderers to use a unified European procurement document to attest that no grounds for exclusion are at hand. Many of the proposed changes are clarifying in nature, and will entail only insignificant changes to the procurement procedures.

However, the proposals include some modifications of interest. Amongst these, we note that the proposal intends to allow for more extensive use of negotiated procedures within the classic sector, which will create more similar conditions for application of negotiated procurement between the classic sector and the utilities sector. The new proposal allows procuring bodies to use negotiated procedures if the contract requires customisation of available solutions on the market. As follows from the considerations in the directive, this would include larger construction projects, consultancy services and larger IT projects. The proposal also introduces a new procurement procedure – *the innovation partnership*, which allows a procuring entity to enter into a partnership with one or more companies with the goal of developing a new product or service. Such an innovation partnership may also include subsequent purchases of the developed product or service.

Already under the 2004 public procurement directive, *central purchasing* bodies were allowed to act as wholesalers. However, the Swedish transposition did not provide for this opportunity. Under the new proposal, the central purchasing bodies will now be introduced with the competence to purchase goods and services intended for sale to other procuring entities. The practical consequences of the proposal remain to be seen, but the proposal has identified that centralised purchases of large volumes of generic products may be suitable for wholesale operations.

The proposal includes clarifications regarding *voluntary grounds for exclusion of tenderers*. For instance, the proposal now explicitly allows for the exclusion of tenderers that have entered into agreements aimed at distorting competition. Furthermore, the proposal allows for exclusion of bidders who have shown deficiencies in the performance of prior contracts with public entities. Although such circumstances could entail exclusion on these grounds already under the applicable legislation, the proposal does provide some clarification. Of more importance are the proposed mechanisms that allow tenderers to avoid exclusion by *self-cleaning*, which may be applicable under certain conditions.

One of the more litigious issues under the applicable legisla-

tion is the question of the extent to which procuring bodies may request tenderers to supplement or clarify tenders.. The proposal suggests that the current limitations, which state that tenderers may only be requested to remedy obvious misprints or miscalculations and other obvious faults in the tender, shall be re-moved and replaced by the more flexible provision provided by the directives, which states that tenderers may be requested to supplement, clarify and complete their tendersas long as the request is in compliance with the principles of equal treatment and transparency. Due to the more flexible wording, the practical consequences of the adjusted provisions will ultimately be decided by the courts. The new wording is still welcome and may entail a less formalistic approach in the review of contested procurements.

The new provisions on *modification of contracts during their term* are another clarification of importance. Under the proposed legislation, the contract sum may be increased by up to 50% of the original contract sum if made necessary by circumstances that could not have been foreseen by a diligent procuring body. Furthermore, even if no unforeseeable circumstances are at hand and provided that the modification does not alter the overall nature of the contract, the contract price may be increased by up to 10% (or up to 15% for works contracts).

The proposal also provides clarification regarding *replacement of contractors* during the contract term. The suggestion provides important clarification in relation to corporate restructuring (brought on by takeovers, mergers, acquisitions or insolvency). The proposals are suggested to enter into force in April 2016. However, the proposals are still under review by the Swedish Legislative Council, after which a formal proposition will be drafted by the government and submitted to the national parliament for final adoption. It should therefore be noted that the proposals as described above may be subject to further modifications.

We would also like to point out that legislative initiatives regarding both the appeal procedure and specific provisions relating to labor law requirements are under processing. It is therefore likely that even with transposition of the new EU directives, further changes to the legal framework for public procurement in Sweden should be expected over the next few years.

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Must the app be CE marked?

This autumn the Swedish Medical Products Agency (MPA) has urged users of medical apps to check that they are CE marked. The Agency has also announced that it may impose a market ban on an app. When does an app become a medical device and in such case, what are the consequences?

Apps that keep track of your body are growing in popularity and the value of the app market is rising every year. The Medical Products Agency (MPA) has increased its focus on these apps and recently announced that this fall it may impose a market ban on an app for the first time. According to the MPA, the app in question has the task of diagnosing a patient's state of health. This means that the app is a medical device that must be CE marked under EU legislation. Since the app is not CE marked, according to the MPA a market ban must be imposed.

Against this background, the MPA has called for medical app users to check that they are CE marked. But what features make an app a medical device?

For something to qualify as a medical device, first and foremost the manufacturer must have a purpose and area of use for the product covered by the definition of a medical device in Section 2 of the Medical Devices Act. For apps, the main criteria are that the products are intended to detect, prevent, monitor, treat or alleviate a disease in humans.

In other words, an app must be CE marked if, according to the manufacturer, it is intended for the diagnosis or treatment of an illness or injury, or if it is intended to examine a physiological process. For example, the app may transfer data from the body, such as body temperature, body weight, heart rate, and various types of ECGs, regardless of whether the data is fed automatically from a sensor or entered manually. An app with health data such as therapeutic values or images that create and convey a basis for diagnosis, or are used to treat a disease in the user, typically has a medical purpose and must then be classified as a medical device. The classification can also apply to apps that are used as aids for people with disabilities.

It should be noted that so-called lifestyle apps, such as apps for exercise and training, normally are not medical devices.

It should also be mentioned that the device itself, for example, the mobile phone that the software runs on, or through, is not a medical device. The manufacturer of the phone did not have a medical purpose for the phone. However, the assessment may be different if the device is converted for an explicit medical purpose.

What happens if an app is classified as a medical device? The rules include requirements that both the product and the manufacturer must meet.

- The app must be CE marked. Through CE marking the manufacturer certifies that it is safe and suitable for its purpose. An app that is a medical device but lacks CE marking can be banned, which the MPA is now considering for a product available on the Swedish market.
- The manufacturer must have systematic follow-up of apps released on the market to ensure that they work as intended.
- The manufacturer must report accidents and incidents, such as an incorrect diagnosis of improper or no treatment.
- The manufacturer must also take the necessary corrective measures to prevent accidents or incidents from happening again.
- Moreover, the manufacturer must report what corrective measures have been taken; for example, an app may have been modified or taken out of use.
- In addition, the manufacturer must comply with personal data legislation, which means that consent must be obtained from the user.

New regulations on medical devices are being processed within the EU. Follow legal developments carefully.

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Facts and figures

Setterwalls has a proud history spanning over 130 years. During that time we have always been cutting edge. That is as true today as it ever was. Setterwalls has undergone substantial expansion over the past 10 years, both in terms of the number of lawyers and practice areas. Setterwalls' dynamic growth and the firm's participation in several high-profile cases and transactions have pushed the firm to its prominent position in the Swedish legal services market. We are now one of the largest law firms in Sweden, employing more than 190 lawyers at offices in Stockholm, Göteborg and Malmö.

Setterwalls is organized into practice groups and trade and industry oriented teams but Setterwalls' lawyers try not to think in compartments. Each problem will have unique features; each client individual goals. So the firm is committed to pulling together multidisciplinary teams from across the firm to find the best solutions in the areas where its clients' businesses encounters the law. Setterwalls provides legal services to all the players in the international pharmaceutical sector as well as manufacturers of medical devices; public authorities and suppliers of health foods. Our clients also include companies within the innovative and speciality pharmaceutical industry.

Setterwalls' is frequently involved in IP litigation and related matters, competition law and public tenders, regulatory issues, commercial legal work and transactions.

With statements from clients *"This is a great team, which is well equipped to assist pharmaceutical companies. The lawyers have the right attitude and the appropriate legal competencies. They fulfil all requests and requirements, and I am very happy with their support."* and *"These lawyers are excellent - they are always available when I need them, and present their knowledge in an understandable way, so we can make good decisions for our business."* Setterwalls' Life Sciences group is top ranked by Chambers Europe 2015

The Life Sciences group has substantial experience in dealing with authorities and has managed a number of important lawsuits in court for our pharma clients, not only concerning patents and trademarks, but also regulatory issues. Our team is a multi-disciplinary team bringing together the experience and expertise from all offices and with in-depth knowledge of the sector.

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