



LICENSING EXECUTIVES SOCIETY
BRITAIN AND IRELAND

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The Newsletter of the Licensing Executives Society Britain and Ireland

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A Better Way to Understand the Activity, Toxicity and IP Risks of Drug Candidates

The challenge of accurately predicting which in-licensing drug candidates will successfully progress all the way through Phase III and on to market is significant. Complex factors including efficacy, ADMET¹, IP position, cost effectiveness, potential value, competition and fit with the corporate portfolio have to be evaluated and business critical decisions made, usually very quickly. One of the best ways to evaluate the likely activity and the scale of the ADMET, safety and IP risks is to look for information about molecules that share similar activities and properties (such compounds are known as bioisosteres). Unfortunately this is considerably more difficult in practice than it should be.

One of the biggest obstructions is simply finding all of the molecules in the literature, in competitor's programmes, commercial databases or even in your own corporate collection that might share the same biological properties. This is because almost all of the tools that we routinely use to search for similar molecules have a fundamental flaw – they use the similarity of the 2D structures of molecules as a direct proxy for the similarity of their properties. The notion is that if two compounds look the same in 2D, they will behave the same. Whilst this is convenient for computer searching, this approach is demonstrably inaccurate and does not give us the right results.

The lack of accuracy in our search tools has profound consequences. We may miss ideal candidates, even those that we have developed, simply because they 'look' (in 2D) too dissimilar to share the same activity. As well as missing potential opportunities, we may end up paying unnecessarily to acquire activities that we already own or miss the fact that bioisosteres have known ADME, toxicity or efficacy issues in a clinical setting, increasing the risk associated with a candidate. We may also fail to protect our own compounds effectively, and find that a competitor puts a bioisostere on market with just enough structural difference to overcome our 2D based Markush patents².

Understanding Activity and Properties

The activity of compounds is known to be independent of 2D molecular structure. It has been realised since the early days of drug discovery that molecules with very different 2D structures can elicit the same biological action. At the same time, small changes even in a single chemical substituent (e.g. a methyl to ethyl group switch) can cause massive shifts in the activity and toxicity of molecules even though their 2D structures remain very similar. The 2D structure is therefore often a poor indicator of the likely biological activity and properties of a molecule.

With a little thought this is obvious - a protein target does not 'see' the atoms and bonds of a drug (its 2D structure) nicely drawn in a manner convenient for chemists and computers, but instead interacts with the electron cloud around the molecule and the physicochemical properties that the compound presents on its

¹ Absorption, Distribution, Metabolism, Excretion and Toxicity – drug properties

² Patents which protect not only a specific molecule or complex substance, but also a larger group of related products, acting as a ring fence to the most important one.

surface. Until recently it has been too difficult to evaluate those properties accurately and quickly enough to use them in finding bioisosteres. This has now changed with the advent of new Field-based methods.

Field Based Molecular Comparison

Instead of relying on 2D structure, Field based methods use the surface properties around molecules to assess their likely activity and properties, regardless of structural similarity. Four molecular Fields are used to describe the electrostatic (positive and negative), steric (shape) and hydrophobic ('fat-loving') properties on the surface of a compound, which are the main contributors to molecular interactions between drugs and their protein targets. The most important regions on the Fields are then substituted with a Field Point. As shown in Figure 1, Field Points provide a highly condensed but accurate representation of the nature, size and location of the critical properties required for binding and instigating a specific therapeutic effect.

The pattern of Field Points contains no structural information and in fact many different structures could potentially generate a similar pattern. Crucially, any molecule that can present that same configuration of Field Points is likely to have the same biological activity. By finding molecules with similar Field patterns to a candidate we wish to evaluate we can find a lot of potentially valuable information, and even possibly an alternate candidate.

The anti-inflammatory example below shows the results of using a Field based search system. The search for molecules matching the steroidal natural ligand identified 23 bioisosteres with 4 distinct chemical scaffolds each with nM- μ M activity. The molecular weight range of the resulting bioisosteres was 300-450, and included no steroids, no toxic flags or outstanding ADME impediments, and all structures showed activity in cell based assays. Patents protecting a number of structures very similar to these results were subsequently filed by other companies.

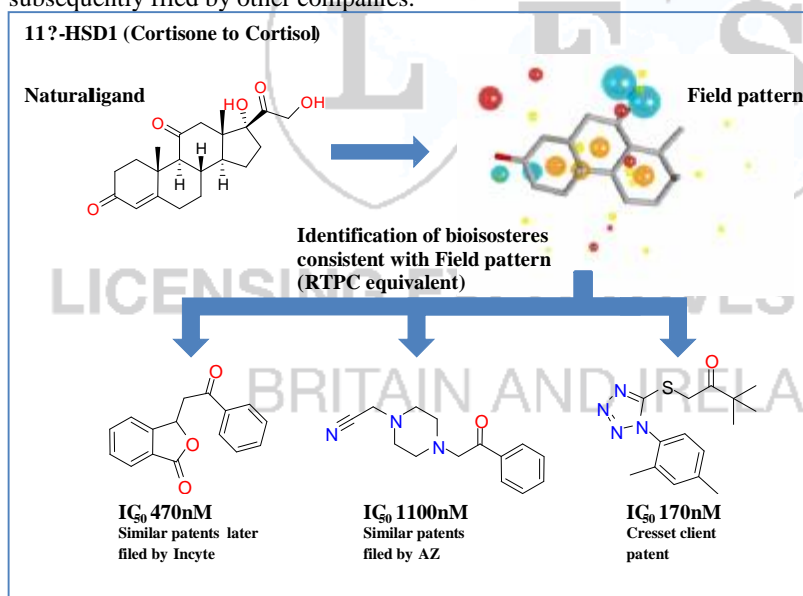


Figure 1. The Generation and use of Field patterns to identify structurally diverse active chemistry from a natural ligand

Choosing and Protecting the Right Molecules

When choosing a new in-licensing candidate it is very useful to understand all of the diverse chemical scaffolds that will display the specific activity and to find the empirical data that are available on those compounds. By using Field-based methods to search all of the available databases, internal and commercial, for information relating to bioisosteres we can quickly build up a detailed picture of the likely ADME, toxicity and efficacy profile of the candidate which we can then use to inform our decisions about its suitability for in-licensing.

To then protect all of our candidates, whether sourced internally or externally, the question becomes, how many different Markush structures are needed to cover the important bioisosteres that are predicted for a given activity? By covering each of these different chemical scaffolds, the development of closely related 'me-too' products can be blocked leading to stronger patent portfolios and potentially extending the period of market exclusivity for new medicines.

Field-based methods offer new tools to help gain a deeper and more rapid understanding of the risks associated with in-licensing candidates as well as potentially identifying new opportunities. They offer a wide range of potential advantages to in-licensing, IP, safety and R&D scientists throughout pharma and biotech.

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President's Diary - October 2009

Renewal is the theme of my contribution to this edition, as we experience renewal in the leadership of two of our committees, anticipate exciting changes at the meeting of LESI's delegates in San Francisco, and ask you all to renew your commitment to your Society's activities in the lead up to the 2011 LESI meeting in London.

Firstly, the changes at committee level: **Darren Olivier** has handed over to **Roman Cholij** as Chair of the Brands Committee and **Ian Hartwell** will be succeeded by **Chris Bartlett** as Chair of the Education Committee. Both are key committees for our organisation. Darren and Ian have done an excellent job in the last few years. We thank them for all their hard work and commitment on our behalf. We look forward to great things from the renewed leadership of Roman and Chris. I have encouraged both of them to tell you a bit about themselves in these pages and to explain how you, as members, can help them achieve their committee's objectives. With 2011 now rapidly approaching, helping **Anne Lane** and her team prepare the LESI conference programme will I'm sure be high on their list. Volunteers are always welcome. The Society needs renewal at all levels. New blood in our committees is no exception. Please put yourself forward if you think you can make the time.

On a related note, **Conan Chitham** has kindly agreed to lead a working group to review (and renew) our website and publicity material. If anyone would like to help on this challenging but very important project, please let Conan or me know.

Secondly, constitutional change: I reported back in the summer on proposals debated at the Manila LESI delegates' meeting on the name/strapline of our Society, and the possible introduction of organisational membership. The proposal to be put to delegates in San Francisco on the first issue is that the name will be retained (it having been established in Manila that "LES" had significant value), but with the addition of

the strapline: “*Advancing the business of intellectual property, globally*”. Britain & Ireland will be supporting this change, and all the indications are that it will be approved. The report of our delegates, which appears elsewhere in these pages will confirm how things end up on this, and on the broader and longer-term debate on the introduction of organizational membership.

Thirdly, renewal of your commitment: like most Society’s, ours has faced a number of challenges during the downturn. Many members have been unable to renew as a result of budgetary constraints, and similar considerations have reduced attendance at some of our meetings. It is widely accepted that focusing on networking and education is critical when the financial climate chills. LES provides excellent opportunities for both, and excellent value for money compared to commercial conferences and many other professional associations. No-one knows when a sustainable upturn will occur. But I for one am convinced that, when it does, those who have continued to contribute actively to our Society will be the winners. And with the 2011 LESI conference to look forward to as one of the best networking and educational events for our members for many years, now is without doubt the time to renew your commitment to our activities.

Nigel Jones, President, LES B&I

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New Members!

Council is pleased to welcome the following new members to the Society:

Mr Simon Abrahams, Maxwell Winward; Mr Simon Black, Gilholm Harrison Ltd.; Ms Megan Compton, Herbert Smith; Mr Chen Haitian, 2083 Lawrenceville Road, Lawrenceville, New Jersey, USA; Mrs Louise Handley, Lee & Priestley; Mr Martin Layton, Intellectual Assets Centre; Dr Louise Platts, Cambridge Cognition; Mr Alex Weedon, UCL Business plc.; Ms Maria Weir, Intellectual Assets Centre.

Members on the Move>>>>

Daniel Guildford
74a Netherwood Road
London W14 0BG

Michael Hill-King
King’s College London Business Ltd
5th Floor Capital House
42 Weston Street
London SE1 3QD

Ceri Mathews
Ploughshare Innovations Ltd
Unit 2, Nile Mile Water
Stockbridge
Hampshire SO20 8DR

Ruth Sutherland
Flat 12, The Firs
Hernes Road
Oxford OX2 7QN

Obituary

Raymond Hamilton 1950-2009*

LES Council was saddened to learn of the untimely death of Ray Hamilton and his wife, Pat, in a car accident on the M6 in April 2009.

Working in Industry throughout his career firstly at Albright & Wilson then BTG, FMC and most recently in the patent department of Pilkington, Ray was noted for his thorough approach with an emphasis on quality work, giving practical and commercially-minded advice to his clients. He was known for his shrewd thinking, his courtesy and sense of humour.

Ray will be much missed by his friends, colleagues and associates.

We extend our sympathy to his family and friends.

- A full Obituary may be found in the September edition of the CIPA Journal

Compulsory Licence Provisions in revised Community Regulation

Last month saw the publication of a revised Council Regulation on the Community patent following discussions in the Working Party on Intellectual Property (Patents). Under Article 21(1) of the Regulation, four years or later after a patent application is filed or three years or later after a patent is granted, a person can apply for a compulsory licence if the patent proprietor has not exploited the patent on reasonable terms or made effective and serious preparations to do so, unless they have a legitimate reason for their inaction. The grant of a compulsory licence must be in the public interest.

Although compulsory licensing regimes already exist in national patent laws the proposals will go further than some existing legislation. For example, in the UK under ss 48 to 54 of the Patents Act 1977, an application for a compulsory licence can be brought after the expiry of three years following the grant of the patent if the patent is not exploited, however, in practice such applications are rarely granted due to the stringent requirements for their grant that must be met (which are set out in the Act).

In addition, under the revised Council Regulation, the exploitation of a Community patent may be authorised at the request of a Member State in times of national emergency or other situations of extreme urgency. Semi-conductor technology, as in the TRIPS agreement, proves an exception to Article 21(1) and can only be exploited without consent in such emergency situations.

Recital 6 states that compulsory licences would mitigate the negative effects of an exclusive right created by a Community patent. However, as expected, its provisions have been highly controversial. The Working Party met to discuss the revisions in early October 2009 and the outcome of their meeting remains to be seen. It is worth noting however that the Community patent legislation has been the subject of negotiation between Member States for a number of years and its enactment is still uncertain.

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LICENSING EXECUTIVES SOCIETY
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Introducing the new Chair of the Brands Committee – Roman Cholij



As the new chairman of the brands committee, I feel very excited about being part of and chair of an extremely talented team of individuals who contribute to a very important part of the business of LES Britain & Ireland, namely bringing a focus on brand licensing and related business issues. Although traditionally the Society has focused on patents and technology licensing, brand licensing is a £116 billion industry and arguably at least of equal importance to the former. Brands are certainly of greater longevity! Technologies come and go, and their IP protection is extremely limited (generally 20 years for patents). Brands, on the other hand, have no such limits. As long as they are nurtured and looked after, their statutory and common law protection goes on and on, and their commercial value can keep growing and growing. BASS & Co's PALE ALE is a registered trade mark and a big brand that was filed as a trademark in 1876 and is still in force over one hundred and thirty years later! The scope of brand licensing is also without limit, covering services as well as products.

About myself

I am particularly looking forward to being involved in the brands committee since by profession I am a trade mark attorney, dealing with trade mark and brand issues on a daily basis, and I have a passion for the education side of things. I have my own firm - Cam Trade Marks & IP Services - based in Cambridge. In the past I have also been an IP manager in a health technology company, and years before that I took a science degree in medical sciences (at UCL) whilst training to be a medical doctor at St George's Hospital Medical School (I did not complete my medical training, but I did become an academic doctor – in fact twice over). That science background enabled me to prepare to be a patent attorney, and I took the equivalent of the CIPA foundation papers. However my greater interest in trade marks led me in another direction. I am also a graduate of the MSc programme in Intellectual Property Management at Queen Mary & Westfield College, London University, during my studies there I became, I believe, the very first 'student' member of LES Britain & Ireland. To earn that privilege I was required to write an article for this publication about my MSc course! Today I am also involved with the educational activities of the Institute of Trade Mark Attorneys (ITMA) – writing quite frequently in their Review - as well as being a committee member of the International Trademark Association (INTA).

Plans for the future

My plans as chair of the brands committee include trying to increase brands 'presence' at the seminars and meetings of the Society, so that our evening meetings (as an example) reflect a little more the realities of the IP market place, and not just technology or pharma licensing. I believe, also, that we should forge closer relations with ITMA, with whom we could hold occasional joint meetings, thereby making LES more attractive to trade mark attorneys, potentially expanding our membership base in this way, too. ITMA is very good on educational activities on the law side of trade marks, but LES could fulfil a valuable alternate and complementary role for ITMA by being the forum of learning for trade mark attorneys and students on the more commercial parts of the business: valuation, licensing, securitisation and so forth.

I would personally also like to see more emphasis on design and copyright licensing (enabling us to give presentations to jewellers, web site designers, film makers, authors, etc), but that's a matter for future discussion and consideration.

Invitation to get involved

I would, finally, like to take this opportunity to invite anyone in the Society with an interest in brands to consider whether they might like to get involved in some committee activities. This would entail coming

along to occasional meetings with your ideas and enthusiasm, and helping me to forge innovative programme ideas to present to General Council. You can then become part of the process of making LES Britain & Ireland even more dynamic and more interesting than it is now!

Please do contact me at roman@camtrademarks.com. I would also welcome hearing from you if you can't or don't wish to be part of the committee but would still like to tell me about your ideas and suggestions.

Roman Cholij, Chair LES B&I Brands Committee

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Christopher Bartlett – the new Chair of the Education Committee



Over the past 20 years I have held various roles with BTG, BT, QinetiQ, ITI and others, covering the whole spectrum in IAM and licensing from the birth of an invention to the generation of commercial licence revenue. Previously I worked in international high-tech sales & marketing, and before that as a development engineer with Pilkington Group where I first became a patentee. Today I am a Member of Council of LES Britain & Ireland, and I am also on the committee of LES in Scotland, so I like to think I have a fairly rounded perspective of the intellectual property environment in all its multifarious guises, mutatis mutandis and including sui generis !!

In taking on the role of Chair of the Education Committee, I want to thank and applaud Ian Hartwell for the excellent work he has done over the past few years in getting it into its current form. I have had the pleasure of working with him on a couple of the recent Fundamentals courses, and my first duty now is to Chair the next course in this series at Cranfield in March/April 2010. Beyond that I hope to be able to continue the development work Ian and others have started on introducing other courses across the UK and Ireland, focusing on commercial management and value-add of intellectual assets, and addressing the real practical issues of costs, course length, location and relevance. All suggestions and requests for specific content will be welcomed!

As an LES International certified trainer I first presented Day 1 of the Fundamentals course in 2006, but my experience in education apart from my own goes back as far as

1976 when I was a lecturer at Durham University. Since moving to the corporate world in 1981 and discovering LES in 1992, I have presented in-house IP training courses to several companies, and over these many years I have continued to learn that the ever-changing world of IP is by far the richest seam of knowledge for those seeking challenge and creativity, invention and innovation. I hope through future LES courses to convey the excitement of that endless evolution.

Christopher Bartlett, Chair LES B&I Education Committee

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In 2004, The LES Foundation, with support from The Licensing Executives Society (U.S.A. and Canada), Inc., hosted its first Graduate Student Business Plan Competition. The event grew quickly in both size and popularity among students in the U.S. and Canada and in 2008, thanks to a partnership with The Licensing Executives Society International (LESI), it “went global” welcoming student participants from around the globe.

The Competition continues to thrive on its reputation for being a world-class event emphasizing IP education, professional mentorship and networking – but with an added sense of community and collegiality that sets it apart from the rest.

Each year participants find that beyond the chance to win incredible prizes, their Competition experience provides a comprehensive education about the importance of intellectual property as part of a successful business strategy, as well as valuable mentoring and networking opportunities with members who readily volunteer to share their input and expertise. Win or lose, the LES Foundation Competition gives each participant a leg up for their future.

Past participants rate LES Competition judges as “second to none.” Each year the Foundation assembles a world-class panel of IP business veterans, who span industry sectors and who share with students valuable expertise, insights and know-how earned in the trenches of start-ups to Fortune 500 companies. In return, our judges find mentoring young entrepreneurs to be incredibly rewarding and invigorating.

The 2010 LES Foundation Graduate Student Business Plan Competition is underway and, thanks to support from LES (USA & Canada) and LES International, the event will again be open to graduate students from across the globe.

Unlike other business plan competitions, the LES experience introduces students to the importance of intellectual property as part of a successful business strategy. The Competition provides each participating team with individualized feedback, mentorship and industry networking opportunities that assure each participant leaves a winner.

The Competition continues to grow in popularity and its success would not be possible without the help of member volunteers. We invite your society’s participation this year! Members can volunteer for a task as

simple as offering to alert local business schools about the Competition to something a bit more involved such as screening and offering feedback on a handful of student business plans. If you have any questions or would like to get involved, please contact me.

Linda Chao

LES Foundation Board Member

Chair, LES Foundation Graduate Student Business Plan Competition

bplan@lesfoundation.org

Phone: + 01 650-725-9408

- *For details of last year's winners see:*

<http://www.lesfoundation.org/competition/results.html#2009>

* * *

News from the Regions

LES Scotland – October 2009 Event

Our October event, held jointly with Wellness and Health Innovation and Interface, provided an excellent insight into the resources that are available for companies in Scotland that seek to develop and bring to market innovative products. The focus of the speakers was on stressing the benefits of knowledge exchange. The event was hosted by LES Scotland Committee member Derek Brown, who welcomed the audience and introduced new committee members Dr Abbe Brown, Lecturer in Information Technology Law at the University of Edinburgh and Craig Thomson of Murgitroyd & Company.

Speakers:

Janette Hughes – Wellness & Health Innovation is an exciting national initiative, designed to support Scottish companies develop innovative products or services for the wellness and health sector.

Janette explained that Wellness & Health Innovation have an important role to play in convincing companies that there is a market opportunity in the growing wellness and health sector. Wellness & Health Innovation are able to provide companies with resources such as market reports to enable them to build a business plan in order to gain funding - help at any stage of the product life cycle – and provide the necessary introductions to keep a business on track to be a success.

Wellness & Health Innovation see that wellness and health products and services for the elderly are increasingly important in a world with a growing proportion of elderly and they see this as a great opportunity for Scottish companies.

Alastair Knox - Viopti Ltd, an innovative company looking to exploit a gap in the contact lens market.

Alastair recounted the story of his start up company from working with Beyonce and Shunsuke Nakamura (he used to work in media), to a brainwave on a long haul flight (where he came up with the idea for his novel contact lens emergency storage product), to IP protection and the brink of an international launch of his product in late 2010 and 2011.

Alastair admits that he never saw himself as an inventor but “just a guy with an idea”. He explained how he sought patent protection by carrying out much of the necessary paperwork himself in the first instance (with plenty of calls to the UK IPO) and then with help from patent advisors. Once he had secured protection for his product the ball really started rolling. Wideblue, who provide support to entrepreneurs with product design, development and manufacturing, were sufficiently impressed by the product to offer their support.

Now after collating a strong team, carrying out market research through the Wellness & Health Innovation centre and creating a business plan the product is on the verge of hitting the market with launch dates set for the UK and USA in 2010 and Canada and the rest of Western Europe in 2011.

Louise Arnold, Interface - the knowledge connection for business

Louise explained that Interface was a matchmaker but despite this there were no awkward silences or bad anecdotes on offer, for Interface is a matchmaker of a different kind, linking businesses with world class expertise, skills and research facilities available in Scotland's Universities and Research Institutes. Interface is funded publicly and provides a free service to companies.

Louise explained that businesses were increasingly recognising the value in using the wealth of expertise in Scotland's 26 Universities and Research Institutes. Interface are experts in identifying the correct party to match companies to and provided many examples of solutions that they can help obtain from student projects to academic consultancy and with a 98% satisfaction rating in 2009 it looks as though the service is set to go from strength to strength.

Notable client companies that have been assisted by Interface are Boots, who ran a series of mini dragons den seminars and Nairns, the oatcake manufacturer, who were looking to reduce fat levels to obtain a longer shelf life.

John Donald, Robop Limited, is an East Lothian based company responsible for developing and marketing the world's first intelligent bird repellent.

John provided a fascinating insight into his bird repellent product and the help he received from Interface in matching Robop to the University of St. Andrews who provided consulting on bird behaviour under a creative licensing agreement.

Robop Limited have created and now sell robotic falcons designed to imitate a peregrine falcon which are known for having a penchant for eating gulls and pigeons and therefore are perfect for those wishing to deter such creatures from their property. The product has now been exported to 15 different countries and is used by companies such as Scottish Widows and in diverse locations from mines to chicken farms.

John explained that to develop their product they required a bird behaviour expert and where Bill Oddie could not assist, Interface could. They found a suitable bird expert (the proverbial needle in a haystack) who was a perfect match for Robop and who helped provide the expertise they needed to develop their product.

Thanks – to Maclay, Murray and Spens LLP who hosted the event at their spectacular new Edinburgh office.

Nat Baldwin, Metis Partners.
Stephen Robertson, LES Scotland Committee

Attention Young Executives!

THE LESI YOUNG MEMBERS CONGRESS IS A TASK FORCE OF LESI CREATED TO MEET THE NETWORKING & PROFESSIONAL NEEDS OF YOUNG EXECUTIVES UNDER THE AGE OF FORTY INTERESTED IN THE BUSINESS OF INTELLECTUAL PROPERTY, INCLUDING LICENSING, SALE, VALUATION & INVESTMENT. PARTICIPATION IN YMC REQUIRES MEMBERSHIP IN GOOD STANDING WITH YOUR LOCAL LES MEMBER SOCIETY.

YOUNG MEMBERS CONGRESS

UPCOMING EVENTS:

Orientation

LES INTERNATIONAL ANNUAL CONFERENCE
APRIL 11-14, 2010
SANDTON, SOUTH AFRICA

Full Program

LES INTERNATIONAL ANNUAL CONFERENCE
JUNE 4-8, 2011
LONDON, UNITED KINGDOM



LICENSING EXECUTIVES SOCIETY
INTERNATIONAL

CONTACT STEPHANIE SILVERSTEIN (SSILVERSTEIN@LES.ORG OR 703.836.0026) TO REQUEST MORE INFORMATION.



**LICENSING EXECUTIVES SOCIETY
BRITAIN AND IRELAND**

"Advancing the Business of Intellectual Property Globally"

Moving Company/ Changing Address?

Please remember to tell our administrator, Jennifer Kirkcaldy, if you change your office address so that we can continue to send you LES information.

LES Administrative Office,
Northern Networking Events Ltd
Glenfinnan Suite
Braeview House
9-11 Braeview Place
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Glasgow
G74 3XH

Please also remember to change your contact details in the membership directory on the LESI website (www.lesi.org). As a service to our members the editor will print any change of company and location in newsXchange™. Please contact Mary Elson, elson.mary@btinternet.com

LICENSING EXECUTIVES SOCIETY

Membership

Enquiries should be addressed to Jennifer Kirkcaldy at the LES Administrative Office:

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Email: les@northernnetworking.co.uk

The membership application form may also be found on the LES B&I website: www.les-bi.org