Godt: Equitable Licenses in University-Industry Technology Transfer GRUR Int 2011, 377

# **Equitable Licenses in University-Industry Technology Transfer**

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*Equitable Licensing* has become a challenge for public research organizations and industry alike. It is required by various philanthropic sponsors, especially in the pharmaceutical sector<sup>1</sup>. However, beyond a few precedents, concepts and individual license clauses are still little conceived. The article explores the issue of "Equitable Licensing", re-iterates the specific role of public research, and discusses three distinct legal problems which arise in university-industry technology transfer relations and impede the potential of Equitable Licensing.

## I. Equitable Licensing

*Equitable Licensing* as a concept has evolved in the political debate about access to essential medicines. The term was first coined when the Yale University renegotiated its license with Bristol-Myers Squibb (BMS) with regard to the HIV-medicament Stavudine (Zerit®) in 2001 (infra II.). Since then, the concept has matured into institutionalized programs like the "Socially Responsible IP Management Program" at UC Berkeley<sup>2</sup>. Its primary focus rests on the improvement of public health in neglected parts of the world or on neglected diseases as such<sup>3</sup>, although in principle, any humanitarian goal could qualify as a goal<sup>4</sup>. Its underlying rationale is not simply "charity"; it is bound to institutional and personal responsibility for publicly funded research, and serves as a means to remedy market failures. Technically, Equitable Licenses build on the proprietary technology transfer from universities to industry, universally labeled as "post Bayh-Dole"<sup>5</sup> (in Germany: "Verwertungsinitiative 2002"<sup>6</sup>). The U.S. "Bayh-Dole Act" of 1980<sup>7</sup> is the heart of a package of laws which triggered the patent supported transfer of knowledge from public research institutions to industry<sup>8</sup>. It is attributed to have fostered new growth in the mid 1980s, and re-maneuvered the sciences towards product development and new organizational forms of research<sup>9</sup> –

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a process which has been copied internationally<sup>10</sup>. The term "Equitable Licenses" is broadly synonymous to "Humanitarian Use Licenses"<sup>11</sup>, "Equitable Access", "Charitable Aims", "Global Access", and to some extent to "two-tired pricing". However, Equitable Licensing differs from other forms of promoting access to medical innovations in five aspects. (1) Equitable Licenses build on contracts (bilateral and multilateral consortia agreements). Therefore, they are distinct from governmental intervention, like compulsory licenses<sup>12</sup>, governmental use<sup>13</sup>, march-in-rights<sup>14</sup>, and the WTO-mechanism of back-to-back export-

import-licenses<sup>15</sup>. (2) The essence of the contract is the transfer of knowledge in one direction, encompassing both, time limited acquisition of rights, and long term research collaborations. Thus, Equitable Licenses are different from collective licensing models like clearinghouses<sup>16</sup>, patent pools<sup>17</sup>, or information platforms<sup>18</sup> which provide mutual access. (3) The term "Equitable License" is confined to the transfer of knowledge from public research institution towards private industry. Thus, purely private agreements between competitors, like the voluntary license initiative of ViiV (a joint project of Pfizer and GSK), are not included<sup>19</sup>. (4) Purely unilateral private actions like the so-called "non-assert pledges" by industry are equally exempt. (5) Equitable Licenses have a clearly envisioned group of beneficiaries, thus, they are not geared to broadly fostering progress in a given sector in contrast to the new creative commons initiatives fostering "green technologies"<sup>20</sup>.

The following article first re-iterates the history of "Equitable Licenses", and develops a typology of "Equitable Licenses" (II.). As the concept rests on the modern role of academic research, it will then explore its newly assigned functions<sup>21</sup>, and position these findings in modern innovation theory (III.). Subsequently, it describes three distinct legal problems with regard to "Equitable Licenses" (IV.), before drawing conclusions (V.) The article is a result of an interdisciplinary research project "Equitable Licenses"<sup>22</sup> funded by the German Volkswagen Stiftung<sup>23</sup>.

## **II. Precedents and Conceptual Diversification**

The idea of "Equitable Licensing" was instigated by the well-known dispute around the AIDS-medicament d4T (Stuvadine, trade name ,Zerit'®) at the Yale University in 2001<sup>24</sup>. D4T was initially discovered in the 1960s at the Detroit Institute of Cancer Research by Jerome Horowitz. In contrast to the originally intended cancer therapies, the researchers Tai-Shun Lin and William Prusoff at Yale found the substance to be effective in treating HIV-patients in the 1980s. Their research was funded by the U.S. National Institutes of Health and Bristol-Myers, followed by a patent filing for the HIV-application in 1986 by Yale University, issued in 1990<sup>25</sup>. The patent was licensed exclusively to Bristol-Myers Squibb (BMS) which finally put Zerit® on the market in 1994. As it was common practice at that time, the medicine was marketed at a uniform prize worldwide. In 2001, the daily dose per patient was available for 11,97 Euro (4.369,05 Euro/year)<sup>26</sup>.

After the medicament was put on the Essential Medicines List by the World Health Organization (WHO), Médecins Sans Frontières (MSF) found the price not sustainable and finally, in February 2001, asked the Board of the Yale University to waive the South African patent. Yale rejected by referring to the exclusive license to BMS.

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At this point, the students of Yale intervened, and had William Prusoff write an editorial for the New York Times technology section in March 2001. Responding to public pressure, Yale asked BMS to grant "patent relief" and price cuts. BMS turned in, signing an agreement with Aspen Pharmacare, a leading South African generic manufacturer in June 2001. Due to generic competition which included imports by the Indian Manufacturer CIPLA the price of d4T dropped by 96% within a year. This allowed MSF to scale up HIV-treatment programs across Africa. A very similar agreement was concluded by Gilead, and the Rega Institute for Medical Research at K.U. Leuven and the Institute of Organic Chemistry and Biochemistry in Prague with regard to the medicament Tenofovir, the active substance of Viread® and Truvada®<sup>27</sup>.

By now these first steps have evolved into explicit "Essential Medicine", resp. "Global Access"-strategies, applied both by private companies like Boehringer<sup>28</sup>, and public organizations like the WHO<sup>29</sup>. An offspring of the Yale student initiative is the foundation of UAEM (Universities Allied for Essential Medicines) with various chapters worldwide<sup>30</sup> which developed a standard form of an "Equitable License"<sup>31</sup>, and instigated the so-called "Philadelphia Consensus Statement"<sup>32</sup> in 2006. In 2009, the University of Edinburgh has adopted an explicit policy statement<sup>33</sup> which basically follows the "non-assert" approach for Least Developed Countries, and "expects" industry partners to "appreciate and cooperate".

Equitable Licenses break down into two subtypes. One subtype is characterized by using "non-assert" clauses. These clauses are used in "Equitable Licenses"<sup>34</sup>, but can also emerge as unilateral social responsibility policy of a single firm<sup>35</sup>. They are part of the diverse differential pricing strategies. Ultimately, they bring down prices by means of competition<sup>36</sup> – providing "freedom to maneuver" while respecting patents<sup>37</sup>. The advantage of the non-assert model is that it keeps enforcement measures to a minimum. Overall, it complements other approaches like the widely used confidential rebates modeled by *P.Danzon/A. Towse*<sup>38</sup>. However, it should be noted that models of confidential rebates have been developed in response to governmental prize controls in the first place<sup>39</sup> (thus, inversely, helping industry to sustain nominal unitary prices). The other subtype of "Equitable Licenses" pursues goals in more explicit terms, usually directed towards one specific country or project, and is not confined to pricing strategies. E.g., the industrial partner commits to supply medicaments at a specific prize, and adds further duties like training in order to build up capacity, or the construction of public facilities (water supply, hospitals) to build up infrastructure.

Overall, "Equitable Licenses" have three characteristics: (1) They build on the initiatives of research institutions responding to their public mission. (2) They are bilateral agreements. (3) They pursue broad aims in the public interest, defined by human rights. The means to achieve their goal range from pricing policies to the fostering of research collaborations focusing on specific diseases. Their core is the growing role of academia in the innovation process.

## **III.** The New Role of Academia

## 1. Taking Stock of Interdisciplinary Theory

A lot of academic literature accounts for the new role of public research. Its characteristics are well described<sup>40</sup>, its influence empirically demonstrated<sup>41</sup>, and modern

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innovation theories acknowledge its growing role. In contrast to the former two separate world's paradigm, economic spillover theory credits the direct influx of knowledge by public research to industry<sup>42</sup>. Modern agglomeration theory is built on the observation of fruitful cooperation of academia and industry which *inter alia* inspired the foundation of technology parks around universities<sup>43</sup>. Similarly, sociological network theory found that the strength of modern networks (including innovation networks) is its "social capital" which is built up by actors with different behavioral rationales<sup>44</sup>. Interestingly, even under modern working conditions different working styles persist<sup>45</sup>. Academic research is still less product-oriented, and much more triggered by the quest for understanding a specific process – in the words of *Robert Merton* "by idle curiosity"<sup>46</sup>. Scientists still tend to be intrinsically motivated; profit maximization is not their driving behavioral force. Management theories caution that organizational arrangements have to safeguard institutional tensions in order to protect "the diversity of cultures", both against the more powerful (here, the short term profit rationale) and against sneaking assimilation.

The reasons for the growing importance of academia shall be briefly summarized: (1) New technologies swept away the old distinction of basic research (to be publically financed), and private research (refinanced by patent secured monopoly prices). (2) The growing significance of science for product development (besides the introduction of new public governance tools like New Public Management) fostered commodification of public research. This development corresponds to the melting of the so-called science commons or their substitution by contractual arrangements<sup>47</sup>. (3) New industrial business models prefer the acquisition of (ready-made) research results with proven economic potential over in-houseresearch. This shift contributed to the outsourcing of research departments (resp. closing of inhouse research facilities), and fostered the commodification (thus contractually transferable) of research results. (4) The increase in globally fragmented production processes did not allow a transfer of knowledge under conditions of secrecy anymore, but required industry to assign information, and to secure its knowledge against growing competitors. (5) Responding to the challenges of the "knowledge society" and the "Bayh-Dole Experience", industrial (and research) policies have fostered closer collaborations between industry and academia. One instrument to support these collaborations has become the patenting of academic research results.

The increasing importance of public research for industry did not, however, result in more private funding of public laboratories. Instead, the share of research finance has shifted towards public funding. Although the cost-split may vary from sector to sector, and absolute numbers are contested<sup>48</sup>, it seems safe to account 47%<sup>49</sup> to 57%<sup>50</sup> of the overall drug discovery investments to public expenditures. These numbers broadly correspond to estimates that 50% of all active components of modern medicines are discovered in public research institutions<sup>51</sup>. In addition, public research is credited for having a disproportionately large therapeutic effect<sup>52</sup>. In some research areas, like diagnostics and vaccines, the public engagement is nominally much higher<sup>53</sup>. There are some fields of research from which industry has pulled back altogether<sup>54</sup>. In response to the latter development, the U.S. Government decided in January 2011 to found a new research center to develop new medicines<sup>55</sup>.

### 2. Patent Functionality in Academia

Research patents are often portrayed as items which secure third stream money for academic institutions (thus complementing backdrops in public funding). Empirical data, however, show that most institutions invest more into technology transfer than they recoup by sales and

royalties, at best licensing income is marginal<sup>56</sup>. Universities often "sit" on their patents because licensing to industry fails<sup>57</sup>, and upholding them only produces additional costs. In addition, theory has acknowledged that the three traditional IP-theories (incentive, social contract, and remuneration)<sup>58</sup> which legitimize the detrimental effects

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of IP on competition and individual freedoms with innovation benefits are not applicable to public research institutions<sup>59</sup>: Academic scientists create knowledge as part of their self-understanding. They continue to be remunerated more by fame than by fortune (*R. Merton*). The social contract idea (the monopoly right is granted in return for publication) does not apply to the behavioral norm of publication in research.

Evidently, the functionality of research patenting is distinct from traditional industrial patenting. Academic patenting caters to the new mission of public research to diffuse knowledge not only by publication and education of students, but by technology transfer to industry. Patents, therefore, have become an *additional* yard stick for academia's performance without transforming each institution into an entrepreneurial university. Yet, patents correspond to additional interests involved in science. For researchers, patents signal inventiveness and high performance<sup>60</sup>, thereby providing access to venture capital. An engagement in technology transfer also provides long-term collaborations with industry (in order to position students, to access additional funding, and ideas/jobs for master-theses). The general public has an interest in transforming research results into products.<sup>61</sup> Institutions (and scientists) supplement public money with private funds. The interest of industrial policy lies in re-aligning science with economic needs. Industry, especially large firms<sup>62</sup>, is interested in access to commodified information<sup>63</sup>.

From a systems theory informed standpoint, patents provide "points of communication(s)" between the (classical) research system and the economy which both function under distinct rationales<sup>64</sup>. The patent "translates" academic knowledge into a commodity, and helps to sort out commercially valuable inventions<sup>65</sup>. It can be deliberately acquired, and be defended against competitors. By specifying the commercial applicability/usefulness in the patent description, the knowledge can easily be accessed by industry. Functionally, the patentability supports research policies and funding regulations which give priority to collaborative arrangements between public research and industry aiming at a mutual influence as "push and pull" partners<sup>66</sup>. The systems description is in line with the observation that public research institutions have not been turned into "entrepreneurial entities". Instead, the new technology transfer offices have become intermediaries between the two worlds functioning as "hinge-joints"<sup>67</sup>. From a regulatory point of view, the assignment of property to research institutions is inducing collaborations between academia and industry.

This new role "in-between" has long been overlooked due to the traditional dialectic private/public distinction. The design of intellectual property was conceived as a trade-off between free competition and property (personified by Schumpeter and Arrow)<sup>68</sup>, compromising an incentive to innovate with the diffusion of technology by free competition. *Before* "Bayh-Dole", knowledge delivered by public research institutions was supposed to produce knowledge as a *public* good, brought about by *public* finance. It was therefore

equated with the public domain by scholars as Schumpeter and Arrow. *After* "Bayh-Dole", the conceptualisation of research has been split. Some equated commodified research with proprietary, entrepreneurial research (*D.B. Audretsch*<sup>69</sup>, *B. Verspagen*<sup>70</sup>). Others stressed the continuing importance of public knowledge<sup>71</sup>, warned against additional market failures<sup>72</sup>, and a decreasing quality of research<sup>73</sup>. Although acknowledging some streamlining effects of the Bayh-Dole Act<sup>74</sup>, many criticize access restrictions<sup>75</sup>

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which they assign to the overall process of research privatisation<sup>76</sup>. Thus, in essence, this second group continues to conceptualize public research as a public good<sup>77</sup>. *Tertium non datur*.

## 3. Technology Transfer Offices

If, however, technology transfer offices are described as intermediaries, a space "in-between" is opened up which aligns them with other modern hybrids like "open source"<sup>78</sup> and the various forms of "commons"<sup>79</sup>. Whereas "open source" and "creative commons" create a public space by contract, technology transfer offices decide between public *or* private. The public research institution can do *both*.

The intermediary function of technology transfer offices, as a result of the third mission of public research institutions, has three consequences: First, technology transfer offices "translate" academic research into a commercial language by writing patents ("translational research"). They secure the identity of the inventors (in the interest of both, the inventor and the future investor), and identify those ideas, which could be "supplied" to the knowledge market. Second, technology transfer offices "decide" (usually together with the responsible board member of the public research institution). In contrast to what is often purported, simply patenting is not the task of technology transfer offices. Their task is to decide whether a patent should be sought. As intermediaries, their task is, *beside* identifying patentable knowledge, to safeguard interests in public research. If in some cases the public good is better served when technology is open to broad use, technology managers have to put the knowledge into the public domain<sup>80</sup>, or license it broadly<sup>81</sup>. In contrast to a firm, the mission of a public research institution is not per se "making profits" or "recouping investments". Third, the intermediary has to secure future property against loss via premature transfer. Currently, technology transfer offices tolerate early transfer to third entities. This way, they lose control over downstream licensing terms. Under certain conditions, the full transfer might very well be a means to effective product development. However, in the majority of cases it will undermine a reflection about licensing terms. This deliberation is part of the institutional responsibility which becomes evident, when funding was once dedicated to a specific research purpose (e.g. for research into neglected diseases endemic to least developed countries). Then, unconditional property transfer is inappropriate because it bears the risk that the patent is either not worked or used for blocking competitors. It is the intermediary's responsibility to conduct the business of technology transfer in a way that the initial goal of access to medicines for the poor will not be undermined by any early transfer.

Consequently, the work of technology transfer offices cannot be measured by license income only<sup>82</sup>. Their mission is the development of useful products, not the generation of profits alone. Public research institutions often profit more from long term commitments than from the "one" single (good) deal with industry. A "good" technology manager strives for long term cooperation<sup>83</sup>, fosters working opportunities for students, and future collaborations which might bring in more finances than one single deal. This is the reason for the emergence of qualitative performance measures of technology transfer offices ("social impact" instead of revenue)<sup>84</sup>.

Overall, these three consequences reinforce the role of public research institutions, and render due respect to their central role in the innovation process.

### 4. Equitable Licenses and Intermediaries

What is the function of Equitable Licenses with regard to the intermediary function of technology transfer offices? Equitable Licensing can support technology transfer, where dayto-day operations will not achieve their goals, namely making academic knowledge available to product developments. The reasons can be manifold. The most important hindrance is that technology transfer is built on standard business rationalities. However, the task of public research is to mitigate market failures, pursue research in areas where the profit incentive is weak, and conduct research in areas in which industry is not interested. Equitable Licenses can complement technology transfer in this regard. In terms of systems theory, Equitable Licenses are a means in the hands of intermediaries to mitigate dysfunctionalities of one of the sub-systems. The economists A. Conti, P. Gaulé and D. Foray analyze humanitarian use licenses similarly: They argue that the licenses might mitigate the market failure by improving optimal pricing in monopolistic markets<sup>85</sup>. Legal analysis will depart from the *telos* of intellectual property for technology transfer, and the role of technology transfer offices. Equitable Licenses can function in various ways. They can help to put (shelved) academic inventions into the process of product development. They provide universities with a means to act up to their public responsibility. "Downstream" and "upstream" actors may, on their own footing, bring in additional rationales. "Upstream", funding institutions may condition their support by "Equitable Licensing terms" (like e.g. the GATES foundation did)<sup>86</sup>. "Downstream", individual researchers can step in with

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their personal motivation to push a research result into the product pipeline. Industry might have an interest to cushion the license deal into its social responsibility program.

All these situations are distinct. Their common characteristic is proprietary transfer of knowledge for which technology transfer offices are responsible. Equitable Licenses are a means to materialize their intermediary responsibility. They are tools to foster the use of patents in areas where the commercial prospects tend to be small but where social gains are high. As publicly funded institutions, public research will continue to be scrutinized for public accountability. Especially for publicly funded research where the market has proven to fail

("neglected diseases"), Equitable Licenses can be the means to control commitments of public funding over time and secure access for those who are meant to benefit in the first place.

## IV. Three legal problems

However, there are substantial legal problems which risk undermining the use of Equitable Licenses. Three of them stand out.

## **1. Preserving University Property**

Equitable Licensing is only possible if the research institution (still) holds the title. In contrast to the US<sup>87</sup>, the transfer of title to academic inventions is allowed in Europe. Any restrictions in public regulations which accompany public funding and control future use of research results have been abolished following the turn to technology transfer since 1998<sup>88</sup>. However, once the title is transferred, Equitable Licensing is made impossible.

### a) Early obligation to transfer

In almost all European countries<sup>89</sup>, a researcher is obliged to notify the responsible university department of an inventive idea. However, some researchers vest a third entity with their inventions, found his/her own company or transfer the invention directly to industry. In many institutions, these entrepreneurial researchers are even praised for being "the better scientists". Universities and research institutions endure or even support it, because the right to the invention is directly put on to the development track. Under this rationale, the notification to the university's technology manager comes second best. Some EU-regulations also foster the establishment of "new entities" in which the property rights to research results are concentrated<sup>90</sup>.

This strategy may lead to a quick product development. Under certain conditions, the transfer might be the only way towards product development. However, once the property right has been transferred, any influence on the licensing terms is lost. The university has to take various interests into account, not just profitability. It is this value decision entrusted to technology transfer offices which is undermined by premature transfer. The institution is deprived of this control when the invention is not notified. The consequence is that the internal guidelines have to require strict notification by researchers, and a documented decision by the technology manager reflecting on his/her reasoning.

### b) Trust-Construction (Anwartschaftsrecht)

The described situation (property assignment to a third entity) is similar to the so-called "trust situation". The point of departure is the legal voidness of early transfer agreements to the detriment of the inventor (in German law: § 22 ArbErfG – which, however, allows for purely contractual promises). The trust conceives the university as the trustee of the patent (a legal construct borrowed from the common law). The consequence is that the university holds the legal title to the patent property (for a while) without being entitled to it on the long run, but it is credited for the invention in patent performance indexes. The procedure is as follows: The university files for the patent and will acquire a legally protected "expectation" on the granting of the patent (in German "Anwartschaftsrecht"). This legally protected expectation ("Anwartschaftsrecht") can be transferred to the industrial partner<sup>91</sup>. After eighteen months, the agency will publish the patent file documenting the research institution as the owner. This is an important reference for universities: Their names can be researched in the patent

agencies' data banks. Contractual arrangements as to when the "real" owner will ask the agency to change the owners' name vary. Some contracts stipulate "after the eighteen months publication", others refer to the point in time when the national filing procedure is transferred to the international phase (PCT-filing). The latter rationale implies the potential issuance of a national patent (presumably securing against the legal consequences of the inventors' protection clause). In the end, the patent will only be issued to the industrial partner.

This practice is not only a challenge for empirical scientists who search for "university patents" in the world's data banks. It also impedes Equitable Licensing as the universities have already lost their proprietary position before the patent was issued.

### c) "Fifty-fifty rule"

Reacting to the complexities of licensing, many universities take resort to model contracts when drafting their licenses with industry. In Germany, various models are discussed<sup>92</sup>, of which the so called "Berlin Contract" (BC) has gained great influence. Whereas the contract as such is purportedly not employed one-by-one, its clauses are often referred to. The 2007 revision of the Berlin Contract (second edition)<sup>93</sup> defines university results as those which are assigned to the university either exclusively or above

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50% (Sec. 6.1.3 BC)<sup>94</sup>. This rule implies the new and simple idea that research results below a share of 50%, and those of precisely 50%, are assigned to industry<sup>95</sup>. This rule has a double consequence. First, the academic contributions of 50% and less will altogether be automatically lost in terms of a proprietary title. Second, an uninformed, consensus driven "fifty-fifty" formulation in contract negotiations can result in a loss of (common or joint) property. The property right to the research result will be directly assigned to the industrial partner.

The goal of this clause is to avoid joint property with its complicated constellations. However, not only does it deprive the universities and public research institutions of their property, but equally important, it also undermines their function as an intermediary in technology transfer. They cannot exercise their responsibilities with regard to balancing conflicting public interests. The arrangement forgoes the competences which are entrusted to the universities by their third mission. Overall, it seems questionable whether such a clause is legally valid in the light of the fundamental rights to research freedom and property (under German law, Art. 5III, Art. 14 German Constitution in connection with § 242 BGB).

## 2. "Compulsory Access Rights"

Another question which has been discussed in European research policy is how far public regulation impedes technology transfer. In August 2010, the League of European Research Universities (LERU) criticized the IP-policy of the European "Innovative Medicines Initiative" (IMI)<sup>96</sup> for its unclear wording which would lead to early loss of university

property to industrial partners<sup>97</sup>. LERU also criticized research use rights for industry which impede later exclusive licensing by universities.

A superficial reading seems to be in line with the argument of this article. However, the goal of LERU is exclusionary control of property, whereas the goal of the IMI-participation rules is providing access to academic knowledge. The LERU-press release does not indicate that any other public policies than property control is pursued. However, I argue that research property which has been publicly funded has public policy implications to which institutions have to respond. Decisions about the exploitation and use of patents by public research institutions have to be based on comprehensible reasoning. Similarly, research funding institutions whose goal is accelerated research may order (free or conditioned) access. Access rights, in principle, speed up scientific progress and enhance research freedom. Therefore, the LERU criticism is to be rejected.

# **3.** Transfer to third parties: Equity obligations "oblivious, ineffective and unenforceable"?

The third legal issue refers to the long time frame between the initiation of collaboration (or just the transfer of patent property) and final product marketing. What happens if the industrial partner becomes acquired and the transfer of the bilateral arrangements will be forgotten? Is there any means to secure the Equitable License against transfer risks? The classic legal solution is to conceive these obligations to have *in rem* effects to those, similar to a servitude which burdens the (registered) immobile property (e.g. everybody's right of way, an "easement"). In contrast to continental law, English judges acknowledge an *in rem* effect of contractual clauses which are meant to benefit third parties as an exception to the privacy principle<sup>98</sup> (the closest equivalent in German law: Vertrag mit Schutzwirkung zugunsten Dritter).

The *in rem* effect of declarations has recently become a legal issue in various contexts. The question is: Do publically proclaimed social responsible self-obligations of multinational corporations have a legal effect on contracts and liability<sup>99</sup>? Various legal concepts are currently discussed for this type of taking out public trust. The parallel to servitudes was first discussed<sup>100</sup>. For licensing pledges made vis-à-vis standardization organizations (FRAND-declaration), a legal parallel to exhaustion has been argued<sup>101</sup>, resulting in the forfeiture of injunction.

In contrast to those modern constellations, the primary question is not the right of a *third* party taking resort to a contract. The very rights of the contracting party are at stake. Traditionally, one would argue that the privacy principle (private autonomy) allocates the responsibility to the party. However, one has to acknowledge the special environment of a public entity. It is almost certain that both, the administrative and the scientific personnel will change in the course of the contract. It seems doubtful whether the institutional memory cautiously keeps track of this kind of obligations. And the scientist who left the institution will have no disposition of the contract. Again, the conceptualization of the technology transfer office as an intermediary turns out to be helpful to pinpoint the issue. It is the task of technology transfer to enable the translation of research results into product development. This implies value decisions with the need to weigh various public interests. If a commitment for Equitable Licenses has been made, a more public mode of exploitation outweighs a purely private one. A consequence is that Equitable License commitments are (and should be) published on the webpages of the institution and the industrial partner. Thus, the commitment becomes public knowledge. Public policy statements by research organizations and industry alike call upon

trust vested in the institution by the larger public from which the new owner benefits. Under German law, one could draw a parallel to the good faith principle which, in these cases, could hinder burden-free acquisition. Under common law, the rule would be that an owner cannot transfer more than he/she has. Where contracts are published, no one can argue that he/she did not know about those commitments made in the public interest. The property/the license comes with an obligation which everybody can know.

## **V.** Conclusion

Equitable Licensing is a modern form of securing technology transfer of public research institutions. It broadens the scope of options for technology transfer. In some cases, Equitable Licensing is a means for technology transfer

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offices to live up to their social responsibility commitments. In other cases, Equitable Licensing is an option to develop desired products where development incentives for industry are weak. Equitable Licensing by public research institutions is a measure to remedy market failures which are inbuilt in the patent paradigm, and a means for public institutions to comply with their "third mission" in responsible ways. Conceptually, Equitable Licensing strengthens technology transfer offices as intermediaries between the academic world and the corporate world as being entrusted with the mission of translating research knowledge into a language which can be absorbed by the market.



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E.g. Bill Gates Foundation, see

<http://www.gatesfoundation.org/about/Pages/guiding-principles.aspx>; commented by *I. Chen*, Thinking big about global health, 124 Cell, 661-663 (2006), also *C.Holtzman*, Puget Sound Business Journal, 13. March 2009, Gates Foundation global access requirement gives researchers a boost and a burden, available <http://uwnews.org/apps/dailyclips/scraped/PSBJ\_2009-03-13\_gates.html>; for the US especially National Institutes of Health (NIH), see also *L.A.Salicrup/I.Fedorkova*, Challenges and opportunities for enhancing biotechnology and technology transfer in developing countries, 24 Biotechnol Adv. 69-79 (2006). <http://ipira.berkeley.edu/socially-responsible-ip-management>, described by *C.Mimura*, Nuanced Management of IP Rights: Shaping Industry-University Relationships to Promote Social Impact, in: R. Dreyfuss/H. First/D. Zimmerman (eds.), Working within the Boundaries of Intellectual Property, Oxford University Press, 2010, chap. 9, and *C.Mimura*, Technology Licensing for the Benefit of the Developing World – UC Berkeley's Socially Responsible Licensing Program, Journal of the Association of University Technology Managers (AUTM) 2006, 15-28.

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In the US, "humanitarian use" incentives comprise other goals like improving agricultural yields, treatments of sanitation or clean water, <<u>http://www.uspto.gov/news/pr/2010/10\_41.jsp></u> (Press release, 20.9.2010, proposing a pilot program, under which patent holders who disseminate their patented technologies for humanitarian purposes would qualify for a fast-track *exparte* re-examination voucher).

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E.g. *N.Baldini*, Implementing Bayh-Dole like Laws: Faculty problems and their impact on university patenting activity, 38 Research Policy 1217-1224 (2009), analyzing the Bayh-Dole Act type laws in Italy, with references to countries like Taiwan and Sweden. Documenting adaptive processes in China, Brazil, and South Africa, *A.So/B.N.Sampat/A.K.Rai/R.Cook-Deegan/J.H.Reichmanetal.*, Is Bayh-Dole Good for Developing Countries? Lessons from the US Experience, 6 (10) PLoS Biol 262 (2008).

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See for the description of the US-law *R.Eisenberg*, Public Research and Private Development: Patents and Technology Transfer in Government-sponsored Research, 82 Virginia Law Review 1663-1752 (1996).

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Catchwords for this development are "start-ups", "venture capital", but encompasses structured forms of co-operations fostered by public funding. Out of a broad literature see just *W. M.Cohen/R.R.Nelson/J.P.Walsh*, Links and Impacts: The Influence of Public Research on Industrial R&D, 48 Management Science 1-23 (2002).

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*J. Reichman*, in: C. Godt (ed.), Lessons to be Learnt in Europe from the International Discourse on Patents & Public Health, 2010, *ibid.* 

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As provided by the Bayh-Dole Act, see A.L.Brewster/S.A.Hansen/A.R.Chapman, supra note 11; also A.So, Is Bayh-Dole Good for Developing Countries? Lessons from the U.S. Experience, Lecture at the Charité in Berlin, 23.4.2009, Power Points to be downloaded <a href="http://www.med4all.org/fileadmin/med/pdf/Anthony\_So-Is\_Bayh-Dole\_Good\_for\_Developing\_Countries.pdf">http://www.med4all.org/fileadmin/med/pdf/Anthony\_So-Is\_Bayh-Dole\_Good\_for\_Developing\_Countries.pdf</a>>.

See <http://www.wto.org/english/tratop\_e/trips\_e/public\_health\_e.htm>, further background information: *F. Abbott/J.H.Reichman*, The Doha Round's Public Health Legacy: Strategies for the Production and Diffusion of Patented Medicines under the Amended TRIPS Provisions, 10 Journal of International Economic Law 921 (2007), for the European perspective: *C. Godt*, The So-called ,,Waiver Compromise" of Doha and Hong Kong: About Contested Concepts of the Nature of the International Intellectual Property System – A Comment, in: I. Govaere/H. Ullrich (eds.), Public Policy and Trade in Intellectual Property Law, 2007, pp. 201-228.

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Essays in Part II of *G.VanOverwalle* (ed.), Gene Patents and Collaborative Licensing Models, 2009.

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The currently most famous one is AIDS-Pool under construction by UNITAID, <<u>http://www.unitaid.eu/en/The-Medicines-Patent-Pool.html></u>. UNITAID was founded in 2006 by five countries with the mission to improve access to treatment for HIV/AIDS, malaria and tuberculosis. The AIDS-patent pool project started 2008, patent contributions will be voluntary. The project is financed by a (voluntary) "tax" on flight tickets, and private funding, e.g. by Bill & Melinda Gates Foundation.

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See press release of 16.7.2010, <http://www.viiv.healthcare.com/media-room/press-releases/2010-07-16.aspx>...

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Like "Eco-patent commons" (<http://www.wbcsd.org/>), a critical analysis provide *B.H.Hall/C.Helmers*, Innovation in Clean/Green Technology: Can Patent Commons Help?, Discussion Paper presented at the EPIP Annual Meeting, held in Maastricht (Netherlands) 20.-22.9.2010, download: <http://ftp.zew.de/pub/zewdocs/veranstaltungen/GreenIT2010/Papers/Hall\_Helmers.pdf>; see also *P.A.David*, Mitigating "Anticommons" Harms to Research In Science and Technology, 2010, SIEPR Discussion Paper No. 10-009 <http://siepr.stanford.edu/system/files/shared/pubs/10-009\_v2.pdf>.\_\_\_\_

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With regard to this focus, I am indebted to *G.VanOverwalle* and *D.Foray* who invited me to the EPIP-conference in September 2009 to talk about the "Equitable Licenses and the Role of Universities". The invitation made me rethink Equitable Licenses departing from a reconstructed (new) role of academia. The usual disclaimer applies.

22

With its own webpage: <a href="http://www.med4all.org">http://www.med4all.org</a>

#### 23

Herewith, I express my gratitude to its support. The foundation is committed to basic, interdisciplinary research, and is not to be confused with the car-manufacturer. The endowment comes from a public re-ordering of the estate of the former Volkswagen after WW II, and it is held by the Federal State and the state of Lower Saxony.

#### 24

#### 25

US patent 4,978,655. Later, BMS filed PCT-applications, authorized by Yale, not only for major Western countries like Europe, Japan and Canada, but – critically, included South Africa, Mexico and Egypt.

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Implemented as "Non-Assert-Agreement". Since 2006, Boehringer Ingelheim e.g. has been offering generic manufacturers in specified countries licenses on a "non-cost" basis. In January 2008 the company reported that seven out of nine firms which were pre-qualified by the WHO "accepted" the Boehringer Declaration for Nevirapin (Viramune®), <http://www.doppelklicker.de/HIV-\_Aids-Medikamente\_fuer\_Entwicklungsländer\_-\_Boehringer\_Ingelheims\_Patentpol.16647.0.html> (last visit 20.2.2011).

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Download: <http://www.essentialmedicine.org/EAL.pdf>; rationale explicated by *Stevens/Effort*, supra note 24, p. 92 et seq.

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See Boehringers policy, supra note 28.

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They change the traditional business model that manufacturers distribute products centrally, eventually world wide through its own controlled distribution channels without regard to national GDPs, at a unitary price.

#### 37

See A.Stevens/E.Effort, supra note 24; A.So/B.N.Sampat/A.K.Rai/R.Cook-Deegan/J.H.Reichmanetal., 2008, supra note 5; for a contextual perspective A.Kapczynski, The Access to Knowledge Mobilization and the New Politics of Intellectual Property, 117 Yale L.J. 804, at 850 (2008), also A.Kapczynski/S.Chaifetz/Z.Katz/Y.Benkler, Addressing Global Health Inequities: An open licensing approach for University innovations, 20 Berkeley Technol Law Journal 1031 (2005).

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*P. M. Danzon/A. Towse*, Differential Pricing for Pharmaceuticals: Reconciling Access, R&D and Patents, AEI-Brookings Joint Center for Regulatory Studies Working Paper

03-7, July 2003 <http://aei-brookings.org/admin/authorpdfs/redirectsafely.php?fname=../pdffiles/phpng.pdf>, commented by *S.Richard*, Differential Pricing of Pharmaceuticals – Lessons from Economic Theory, in: C. Godt (ed.), 2010, supra note 12.

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("Mehrsystemzugehörigkeit"/"Multifunktionalität") (p. 32) is the essence of the thesis.

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*M. Osterloh*, Open Source Development – Just Another Case of Collective Invention?, 36 Research Policy 157-171 (2007); for patents: see the Open Innovation Network (OIN), see *M.L.Montagnani*, Open Source Software, Patents and Royalty-free Licensing, 2009, download: <a href="http://www.epip.eu/conferences/epip04/files/MONTAGNANI\_Marialilla.pdf">http://www.epip.eu/conferences/epip04/files/MONTAGNANI\_Marialilla.pdf</a>

#### 79

Ranging from a fixed (royalty-free) access model like in EcoPC (<http://www.wbcsd.org>), to more dynamic (selective, including royalty) models like GreenXchange (under the umbrella of "Creative Commons").

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"Top down" as B.N.Sampat coins it (supra note 3), p. 16.

#### 87

18 U.S.C. § 202, para. C (7) (A).

#### 88

*C. Godt*, 2007, supra note 10, p. 165 seq.

Differences persist with regard to the primary assignment of the right. In Germany (like in the US and Japan), the property right is assigned to the (employed) invento

(like in the US and Japan), the property right is assigned to the (employed) inventor in the first place, but the employer has the right to claim it (in Germany: § 42 Employees Inventions Act [,,Arbeitnehmererfindungsgesetz"]). A special rule which once entitled university professors with the right to the invention was abolished in 2002. In contrast, Italy introduced the entitlement of university professors in 2005 (Art. 65 of the Code of Industrial Property; Dec. Leg. of 10.2.2005, no. 30). In France, Spain, and the United Kingdom, and as general rule also in Italy, the title is directly vested in the employing institution, *M. Trimborn/B. Fabry*, Das Recht des Arbeitnehmererfinders in der internationalen Übersicht, Mitteilungen der deutschen Patentanwälte 2009, pp. 529-539. ▲

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EC-Commission, Guide to Intellectual Property Rules for FP7 Projects, p. 39 (download: <ftp://ftp.cordis.europa.eu/pub/fp7/docs/ipr\_en.pdf.>.\_\_\_

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A European public-private partnership, involving industry, the research community and public authorities, based on Article 187 TFEU <a href="http://www.imi.europa.eu/>.\_\_">http://www.imi.europa.eu/>.\_\_</a>

#### 97

Press release 2.9.2010, download under <http://www.leru.org/files/general/LERU\_Letter%20on%20IMI\_2010%2009%2002.p df>.\_\_\_\_

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Court of Appeal in *Adlerv.Dickson(TheHimalaya)* [1954] 2 Lloyd's Rep 267, [1955] 1 QB 158.

#### 99

For a conditioned yes, see the PhD-thesis of *C. Glinsky*, Die rechtliche Bedeutung privater Regulierung globaler Produktionsstandards, forthcoming with Nomos.

#### 100

O. Robinson, Personal Property Servitudes, 71 U.Chi. L.Rev. 1449-1523 (2004).

#### 101

See *H.Ullrich*, Patent and Standards – A Comment on the German Federal Supreme Court Decision *OrangeStandard*, 41 IIC 337-351 (2010); *ibid*, Patente und technische Normen: Konflikt und Komplementarität in patent- und wettbewerblicher Sicht, in: M. Leistner (ed.), Europäische Perspektiven des Geistigen Eigentums, 2010, pp. 14-95, 77 et seq.