issuance) knowledge.[1143] Thus, the improvement may be a non-obvious improvement at its time of filing, and yet equivalent in light of later arising knowledge. Later arising knowledge might also cause obviousness of the improvement.

VI. Use of compounds identified through 3-D protein structure screening methods

The final question to be analyzed is whether the use of compounds obtained through an *in-silico* screening process infringes the patent that was granted to the screening process itself. As a first step, a recent case related to compounds that have been identified by a patented method and later been imported into the country where the existing patent was originated will be presented. Then, several approaches to the protection of identified compound will be examined.

1. Protection as product of patentable process

Infringement is constituted if identified compounds can be classified as products of a patented process.[1144] Under Art. 64 paragraph 2 EPC and § 9 paragraph 2 No. 3 GPA, a patent to a patented process "shall extend to the product directly obtained by such process." German and other European courts distinguish between patents directed to manufacturing processes or working processes.[1145] Manufacturing processes aim to make a physical product, and the patent to the process extends to such a product. In contrast, a working process does not result in a product, but is typically conducted for the purpose of achieving an abstract result of an action ("abstrakter Handlungserfolg").[1146] A product which is obtained directly from a patented process is the product with which the process ends.[1147] A compound can still be considered

1143 Sarnoff, Joshua, The Doctrine of Equivalents and Claiming the Future after Festo, 14 The Federal Circuit Bar Journal 2004, 403, 410.

1144 Benkard/Jaenstaed, EPÜ, Art. 64, No. 19; also Clark, Vici, Reach-through infringement: what are the limits?, 6 Bio-Science Law Review 2000/2001, 249, 250.

1145 BGH, 11 IIC 236 (1980) – Color Picture Tubes (Farbbildröhre); Benkard/Jaenstaed, EPÜ, Art. 64, No. 24; Benkard/Scharen, Patentgesetz, § 9, No. 53.

1146 Straus, Joseph, Reach-through claims and research tools as recent issues of patent law in: Estudios sobre propiedad industrial e intellectual y derecho de la competencia, Curell Suñol, M./et al. (Eds.): Grupo Español de la AIPPI, Barcelona, 2005, 921, 928.

1147 BGH 8 IIC 147 (1995) – Alkylendiamine I; UK Court of Appeal, 11 IIC 591, 591 (1998) – Pioneer Electronics Capital Inc. v. Warner Music Manufacturing Europe ("Under European law, a product obtained directly by means of a patented process is the product with which the process ends"). A classification of what is considered "directly obtained" is made based on two major approaches, namely the "Chrononological approach" (Chronologischer Ansatz) and the "Theory of Properties" (Eigenschaftstheorie). See Beier, Friedrich-Karl/Ohly, Ansgar, Was heißt "unmittelbares Verfahrenserzeugnis"? - Ein Beitrag zur Auslegung des Art. 64 (2) EPÜ, GRUR Int. 1996, 973. See also Benkard/Scharen, Patentgesetz, § 9, No. 53; Benkard/Jaenstaed, EPÜ, Art. 64, 25.

the direct result of a patented process after having undergone further modifications, provided it retained its identity and did not lose its fundamental characteristics. [1148]

With regard to the subject under consideration, *in-silico* screening processes are directed to the finding of potential binding ligands. Such information is used for drug design. The actual drug, however, is not made out of the *in-silico* screening process. Without being directed to the manufacture of a physical good, *in-silico* screening processes must be considered mere working processes. The screening process does not end with the manufacture of the identified compound, but rather with the acquisition of information about the binding properties of such compound. Identified compounds do not share the identity of the patented screening operation as patented subject matter. In conclusion, patents to *in-silico* screening methods do not provide a patent protection that covers potentially screened compounds.[1149] Thus, uses of identified compounds do not constitute infringement of screening process patents.

2. The Bayer v. Housey Case

U.S. patent law is also familiar with the extension of a process patent to the product which is generated by the process. The Federal Circuit decision *Bayer v. Housey*[1150] raised the question of whether the importing of knowledge that is disclosed with the assistance of a patented process in a foreign country infringes the patented process as such.[1151] The critical law is Section 35 U.S.C. 271 (g) which lays down that "whoever without authority *imports* into the United States … a product, *which is made by a process patented in the United States,* shall be liable as an infringer". [1152] The claim at issue in *Bayer/Housey* reads as follows:

> 1. A method of determining whether a substance is an inhibitor or activator of a protein whose production by a cell evokes a responsive change in a phenotypic characteristic other than the level of said protein in said cell *per se*, which comprises (n steps)
>
> (a) providing a first cell line which produces said protein and exhibits said phenotypic response to the protein;

1148 Bruchhausen, Karl, Sind Endprodukte unmittelbare Verfahrensprodukte eines auf die Herstellung eines Zwischenproduktes gerichtenten Verfahrens?, GRUR 1979, 743, 744.

1149 See Pioneer Electronics Capital Inc. v. Warner Music Manufacturing Europe GmbH [1997] R.P.C. 757; Wolfram, Markus, 'Reach-Through Claims' and 'Reach-Through licensing' - Wie weit kann Patentschutz auf biotechnologische Research Tools reichen?, Mitteilungen der deutschen Patentanwälte 2003, 57-64.

1150 Bayer v. Housey, 340 F.3d 1367-1378 (Fed. Cir. 2003).

1151 Bayer v. Housey, 340 F.3d 1367, 1371.

1152 Bayer v. Housey, 340 F.3d 1367, 1371.

(b) providing a second cell line which produces the protein at a lower level than the first cell line, or does not produces the protein at all, and which exhibits said phenotypic response to the protein to a lesser degree or not at all;

(c) incubating the substance with the first and second cell lines; and

(d) comparing the phenotypic response of the first cell line to the substance with the phenotypic response of the second cell line to the substance.[1153]

Housey alleged that the knowledge *Bayer* obtained from the process of the patent as such is a product. *Bayer* argued that "made" means "manufactured" and that information is not a manufactured creation.[1154] Because of the definition of the term "being made by a process" was ambiguous, the Court interpreted other provisions of the Omnibus Trade and Competitiveness Act of 1988 (which referred to Section 271(g)), finding several indications that the term "made" had to be understood as "manufactured" and applied only to physical goods.[1155] Housey asserted that Congress when said "manufactured" in all cases it was referring to manufacturing. Thus, when saying "made", Congress must have intended something else.[1156] The Federal Circuit was not persuaded, stating that Congress is permitted "to use synonyms in a statue".[1157] The court further stated, "Housey's position suggests an unrealistic level of clarity in congressional word selection"[1158]. Analyzing the legislative history, the court came to the same conclusion that "made" is synonymous to "manufactured". The court further reasoned,

"reading the statue to cover processes other than manufacturing processes could lead to anomalous results. The importation of information … cannot be easily controlled. As Bayer points out, a person possessing the allegedly infringing information could, under Housey's interpretation, possibly infringe by merely entering the country …. Such an illogical result cannot have been intended."[1159]

The court found that if the Congress had intended to give the provision a different meaning, they had to establish appropriate legislation.[1160] The court also considered Housey's assertion that Bayer's drugs were goods made by its proprietary screening methods, holding that the case must be distinguished from *Bio-Technology General Corp. v. Genentech*, where the CAFC had concluded "that a protein made by a host organism expressing an inserted plasmid was a product 'made by' the patented

1153 Bayer v. Housey, 340 F.3d 1367, 1369.
1154 Bayer v. Housey, 340 F.3d 1367, 1371.
1155 See also Liebert, Mary Ann, Information is not physical goods, 22 Biotechnology Law Report 2003, 619-620.
1156 Bayer v. Housey, 340 F.3d 1367, 1373.
1157 Tyler v. Cain, 533 U.S. 656, 664 (2001); Bayer v. Housey, 340 F.3d, 1367, 1373.
1158 Bayer v. Housey, 340 F.3d. 1367, 1373.
1159 Bayer vs. Housey, 340 F.3d., 1367, 1377; see also Paul v. Davis, 424 U.S. 693, 698-99, 96 S.Ct. 1155, 47 L.Ed.2d 405 (1976).
1160 Bayer v. Housey, 340 F.3d 1367, 1376.

process for creating the plasmid itself".[1161] By contrast, the court concluded, the patented process in *Bayer* is not used in the actual design of the drug. As the lower court had noted "processes of identification and generation of data are not steps in the manufacture of a final drug product."[1162] Thus, the Court concluded that the product of *Bayer* does not fall under Section 271(g).[1163] Infringement under Section 271(g), the court explained, is limited to the manufacture of physical goods. It does not extend to knowledge that is generated by a patented process. Therefore, the Court stated that the dismissal of Housey's claims of infringement of patents covering methods of screening compounds that have particular characteristics must be affirmed.[1164] In sum, the reasoning set forth by U.S. courts resembles the situation existing under the EPC and the GPA.[1165] Patents to screening processes do not extend to compounds identified by these screening processes.

VIII. Concluding Remarks

The foregoing shows that patent owners who often find themselves in an interdependent relationship, are able to balance their interests through cross-licensing agreements.[1166] This applies with regard to selection inventions where the broad

1161 Bio-Technology General Corp. v. Genentech, Inc., 80 F.3d 1553, 1561 (Fed. cir. 1996); Bayer v. Housey, 340 F.3d, 1367, 1377-1378.

1162 Bayer AG, 169 F. Supp 2d. at 331; Bayer v. Housey, 340 F.3d 1367.

1163 Liebert, Mary Ann, Information is not physical goods, 22 Biotechnology Law Report 2003, 619-620. The Housey patents were rendered invalid in Housey v. AstraZeneca, 366 F.3d. 1348: Housey sued AstraZeneca alleging infringement of its four patents to screening methods related to protein inhibitors and activators. The district court construed the definition of "inhibitor or activator" to include substances that both directly and indirectly affect a protein of interest. Housey then stipulated that, if this construction were not reversed or modified on appeal, its patents would be invalid and not infringed. The district court came to a final judgment of invalidity and non-infringement. The Federal Circuit held that the claim construction of the district court regarding the "inhibitor or activator of a protein" was properly concluded and thus affirmed the decision. Consequently, the Housey patents were affirmed as invalid and not infringed. One judge (Newman) dissented. Housey, 366 F.3d 1348, 1349.

1164 Bayer v. Housey, 340 F.3d 1367, 1378.

1165 Chapter 4 C VII 1.

1166 Another mechanism by which companies may achieve synergies is the creation of patent pools. This practice allows companies practicing related technologies to assign or license their patents and establish a "clearing house for patent rights", Sung, Lawrence M./Pelto, Don J., The Biotechnology Patent Landscape in the United States as we enter the New Millennium, 1 The Journal of World Intellectual Property 1998, 889-901. In exchange for access to a patent pool, patentees retain their respective patents and license them non-exclusively to others. Licensing is made either directly or through an administrative intermediary created for the purpose. Patent pools are subject to close scrutiny for possible anti-trust violations and therefore must demonstrate that they have strong 'pro-competitive' effects. OECD, Genetic Inventions, Intellectual Property Rights and Licensing Practices, Paris 2002, 66.