Predicting Name Confusion Errors: Or Trademarks 'By the Numbers'

Bruce L. Lambert, Ph.D.
University of Illinois at Chicago
lambertb@uic.edu
(312) 996-2411

PhRMA Trademark and Copyright Committee Meeting Wednesday, December 16, 1998

Pfizer Headquarters

New York, NY

Acknowledgments

- This work is supported in part by grants and contracts from the U. S. Pharmacopeia, the Drug Information Association, the Institute for Safe Medication Practices, the U.S. Food and Drug Administration, and the UIC Campus Research Board.
- The U.S. Pharmacopeia graciously provided the author with electronic versions of the *USP DI–Volume I* and the *USAN Dictionary*.
- The assistance of Swu-Jane Lin, Sanjay Gandhi, Ken-Yu Chang, Dan Boring, Mike Cohen, Bill Brewer, Gary Dell, Keith Johnson, Diane Cousins, Don Rucker and Alan Baddeley and others is gratefully acknowledged.

Some Thought Experiments and Challenging Analogies

- Similarity is a kind of 'cognitive toxicity'
- Look-Alike/Sound-Alike errors are analogous to drug interactions (i.e., similar drugs interact in memory to cause confusion)
- Drugs are physical, material substances, but they are also abstract, information objects (i.e., drugs exist in physical space and in cyberspace)

Similarity as Toxicity

- Toxicity testing is a necessary evil
- Bad toxicity results can kill a promising drug
- No company would consider not doing toxicity testing
- Similarity is a kind of toxicity
- Similarity has its ill effects on memory, perception, and action
- Bad similarity results might kill a promising name
- No company should consider not doing 'cognitive toxicity' tests

<u>Look-Alike/Sound-Alike Errors as Drug Interactions</u>

- LASA errors are a kind of drug interaction
- Similar names interact in the brain/mind to cause errors in memory, perception, and action
- Presence of these interactions can be just as hazardous as 'real' drug interactions
- Must attempt to screen for and avoid such interactions

Material Substances vs. Information Objects

- Most of the safety testing of drugs focuses on their physical and biochemical properties.
- Now and increasingly in the future, drugs will also exist as information objects in cyberspace
- It may someday be more common to encounter a drug as an information object than as a material/physical object
- Must begin to explore drugs as information objects
- Must understand the 'kinetics' and 'dynamics' of drugs-asinformation-objects
- Must avoid collisions/confusions in cyberspace
- Need 'zone-of-safety' in cyberspace around each drug product

The Need for Change in Safety Studies of Nomenclature

- Advances in basic science often necessitate innovations in biological studies, safety studies, and formulation studies (e.g., once upon a time, drugs weren't tested on women or minorities, studies of teratogenicity were not routinely done, etc.)
- There have been advances in the basic science of psychology that necessitate new kinds of safety testing of nomenclature
- We now know (in fairly great detail) how short term memory for verbal information works and how visual and auditory perception of words work
- We are now compelled to make innovations in safety testing of nomenclature that take into account the advances in basic science

Problems with Current Name Approval System

- Arbitrary
- Subjective
- 'Trademark roulette'
- Confusing names still occasionally get through
- Non-confusing names may get rejected
- Screening for safety versus screening for legal registration

Potential Benefits of Computer Screening

May eliminate subjectivity and arbitrariness

- May reduce probability of approving confusing names and/or rejecting non-confusing names
- Provides a scientific basis for name approval decisions that is similar, if perhaps not as well-developed as scientific basis for traditional efficacy and safety studies

Potential Risks of Computer Screening

- Replace human, arbitrary decisions with automated, computerized arbitrary decisions
- FDA or others (EMEA) may impose simple-minded, inflexible cutoffs to determine acceptability of proposed names
- Computer screening may make it even harder to get a global mark
- Computer model may (almost certainly will) make mistakes (e.g., false positives, false negatives)
- Computers may take work from trademark attorneys (!!)
- No standard search algorithm or database of names. Search results depend on search algorithm and database being searched (garbage in/garbage out).
- Liability concerns (are search results discoverable?)

How Do We Maximize Benefits and Minimize Risks?

- Output of computer search should be input to expert (legal and practitioner) review
- Strict cutoff values should be avoided until sufficient, credible, scientific evidence is presented to justify a given cutoff
- A reference standard database of names should be created. Searches against this database would form the basis of name approval decisions, but decisions should be made by panels of experts

So Who Uses Lambert's System?

- ISMP (Med-Errs, Predict)
- USAN (beginning in early 1999)
- FDA (not officially or routinely)

What (If Anything) is Special About Lambert's System

- Algorithms and similarity measures reported in 1997 paper are well known and similar to those used by commercial trademark search firms
- Lambert searches USP-DI, USAN Dictionary, USPTO category 005 (pharmaceuticals)
- Lambert's searches are only a part of ISMP safety screening
- Lambert's methods have been empirically evaluated: numerical similarity scores can be directly related to probability/odds of error
- Lambert's methods are based on sound psycholinguistic theory

Summary: What Do I Think Should be Done?

- Change the way we think about trademark screening from emphasis on legal registration and intellectual property protection to emphasis on patient safety
- Build the scientific basis for name approval decisions
- Combine computer search and expert review
- Develop reference standard databases of names (help from T&T, IMS, etc.)
- Submit search results to relevant agencies with name approval request
- Work together to address multiple competing interests